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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1107

[Docket No. FDA-2016-N-3818]

RIN 0910-AH89

Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this final rule to provide additional information on the content and format of reports intended to demonstrate the substantial equivalence of a tobacco product (SE Reports). The final rule also establishes the general procedures FDA intends to follow when evaluating SE Reports, including procedures that address communications with the applicant and the confidentiality of data in an SE Report. The final rule will provide applicants with more certainty and clarity related to preparing and submitting SE Reports.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-5700.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson or Nathan Mease, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control

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I. Executive Summary

A. Purpose of the Final Rule

This final rule provides further information on the content and format of SE Reports, including the information that SE Reports must contain. FDA is finalizing this rule after reviewing comments to the proposed rule (84 FR 12740, April 2, 2019), as well as the SE review experience the Agency has gained since enactment of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31). As explained in the proposed rule, the SE Reports that FDA has seen to date range widely in the level of detail included, with some reports including very little information on the comparison of the new tobacco product with a predicate tobacco product and some including much more. This final rule will provide applicants with a better understanding of the level of detail that an SE Report must contain. The final rule also addresses issues such as FDA communications with the applicant, the retention of records that support the SE Report, confidentiality of SE Reports, and electronic submission of the SE Report and amendments.

B. Summary of the Major Provisions of the Final Rule

Under the final rule, an SE Report must provide information comparing the new tobacco product to a predicate tobacco product, including information that will enable FDA to uniquely identify the new tobacco product and the predicate tobacco product, as well as comparison information. The requirements will help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (as required by section 910(a)(2)(A) of the FD&C Act).

In addition, the rule explains how an applicant can amend or withdraw an SE Report, and explains how an applicant may transfer ownership of an SE Report to a new applicant. The rule

also addresses FDA communications with applicants on SE Reports and explains FDA review cycles and FDA actions, including the issuance of orders and the rescission of orders. The rule also establishes the length of time records related to the SE Report must be maintained, describes FDA's disclosure provisions, and requires electronic submission of SE Reports, unless the applicant requests and is granted a waiver.

C. Legal Authority

This rule is being issued based upon FDA's authority to require premarket review of new tobacco products under sections 905(j) and 910(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387e(j) and 387j(a)), FDA's authority to require reports under section 909(a) of the FD&C Act (21 U.S.C. 387i(a)), FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c), as well as FDA's rulemaking and inspection authorities under sections 701(a) and 704 of the FD&C Act (21 U.S.C. 371(a) and 374).

D. Costs and Benefits

This final rule would impose incremental compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from $0.4 million to $3.4 million, with a primary estimate of $1.9 million at a 3 percent discount rate, and from $0.4 million to $2.9 million, with a primary estimate of $1.6 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from $0.05 million to $0.39 million, with a primary estimate of $0.22 million at a 3 percent discount rate and from $0.06 million to $0.42 million, with a primary estimate of $0.23 million at a 7 percent discount rate.

The incremental benefits of this final rule are potential time-savings to industry and cost-savings to government. The final rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product.

Certifying may save applicants time in preparing their SE Reports. We anticipate shorter review times for SE Reports as a result of this final rule. In addition, based on our experience with prior SE Reports, we believe this final rule will lead to higher quality SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which will result in cost-savings. We estimate that the present value of government cost-savings ranges from $15.1 million to $150.6 million, with a primary estimate of $50.2 million at a 3 percent discount rate, and from $12.4 million to $124 million, with a primary estimate of $41.3 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from $1.8 million to $17.7 million, with a primary estimate of $5.9 million at both 3 and 7 percent discount rates.

The qualitative benefits of this final rule include additional clarity to industry about the requirements for the content and format of SE Reports. The final rule would also establish the general procedures we will follow in reviewing and communicating with applicants. In addition, this final rule would make the SE pathway more predictable.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation	What it Means
ANPRM	Advance Notice of Proposed Rulemaking
CCS	Container Closure System
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco
CTP	Center for Tobacco Products
DQPH	Different Questions of Public Health
ENDS	Electronic Nicotine Delivery System
EA	Environmental Assessment
E.O.	Executive Order
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSC	Fire Standard Compliant
FOIA	Freedom of Information Act
GRAS	Generally Recognized as Safe
HPHC	Harmful and Potentially Harmful Constituents
HTP	Heated Tobacco Products
MDSS	Manufacturing Data Sheet Specification
NEPA	National Environmental Policy Act of 1969
NSE	Not Substantially Equivalent
PDU	Power Delivery Unit
PM	Particulate Matter
PMTA	Premarket Tobacco Application
PRA	Paperwork Reduction Act of 1995

Abbreviation	What it Means
QRA	Quantitative Risk Assessment
RIA	Regulatory Impact Analysis
RYO	Roll-Your-Own
SE	Substantial Equivalence
TPMF	Tobacco Product Master File
TSNA	Tobacco-Specific Nitrosamines
VOC	Volatile Organic Compound

III. Background

The FD&C Act, as amended by the Tobacco Control Act, generally requires that before a new tobacco product may be introduced into interstate commerce for commercial distribution in the United States, the new tobacco product must undergo premarket review by FDA. Section 910(a)(1) of the FD&C Act defines a "new tobacco product" as: (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

The FD&C Act establishes three premarket review pathways for a new tobacco product:

- submission of a premarket tobacco application under section 910(b);
- submission of a report intended to demonstrate that the new tobacco product is substantially equivalent to a predicate tobacco product under section 905(j)(1)(A) ("SE Report"); and
- submission of a request for an exemption under section 905(j)(3) (implemented at § 1107.1 (21 CFR 1107.1)).

Under section 910(a)(2)(B) of the FD&C Act, a manufacturer of a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, that submitted an SE Report[1]

[1] In this rule, FDA refers to "SE applications" as "SE Reports," but the terms both refer to a premarket submissions under section 905(j)(1)(A) of the FD&C Act.

prior to March 23, 2011, may continue to market the tobacco product unless FDA issues an order that the tobacco product is not substantially equivalent ("provisional" tobacco products). For any new tobacco product introduced or delivered for introduction into interstate commerce for commercial distribution on or after March 22, 2011, or for which a substantial equivalence report was not submitted prior to March 23, 2011, a manufacturer must first submit a premarket application for the new tobacco product to FDA, and FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act, before the product may be introduced into commercial distribution. If a new tobacco product is marketed without an order or a finding of exemption from substantial equivalence, it is adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

Since the enactment of the Tobacco Control Act, FDA has received thousands of SE Reports, many of which lacked the information necessary for FDA to make a substantial equivalence determination. To assist applicants in better preparing an SE Report, on April 2, 2019, FDA issued a proposed rule to provide additional information regarding the content and format of reports intended to establish the substantial equivalence of a tobacco product. FDA received about 100 comments to the docket for the proposed rule, including comments from tobacco product manufacturers and trade organizations, retailers, representatives of tribes/tribal organizations, public health groups, individual consumers, and other submitters. We summarize and respond to these comments in section V of this rule. After considering these comments, FDA developed this final rule, which includes changes made in response to the comments.

IV. Legal Authority

As described in the following paragraphs, FDA is issuing this rule to address the content, form, and manner of reports intended to demonstrate the substantial equivalence of a new tobacco product to a predicate tobacco product. The rule also addresses record keeping, reports,

and the information essential to FDA's implementation of the FD&C Act. In accordance with section 5 of the Tobacco Control Act, FDA intends that the requirements established by this rule are severable and that the invalidation of any provision of this rule would not affect the validity of any other part of this rule.

Section 910(a)(2) of the FD&C Act requires a new tobacco product to be the subject of a premarket tobacco product application (PMTA) marketing order unless FDA has issued an SE order authorizing its commercial distribution or the tobacco product is exempt from substantial equivalence. To satisfy the requirement of premarket review, a manufacturer may submit a report intended to demonstrate the substantial equivalence of a new tobacco product to a predicate tobacco product under section 905(j) of the FD&C Act. Section 905(j) provides that FDA may prescribe the form and manner of the substantial equivalence report, and section 910(a)(4) of the FD&C Act requires that as part of the 905(j) report, the manufacturer provide an adequate summary of any health information related to the new tobacco product or state that such information will be made available upon request.

Based on the information provided by the applicant, section 910(a)(3)(A) of the FD&C Act authorizes FDA to issue an order finding substantial equivalence when FDA finds that the new tobacco product is in compliance with the requirements of the FD&C Act and either: (1) has the same characteristics as the predicate tobacco product or (2) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to regulate the product under the PMTA provisions because the product does not raise different questions of public health.

Section 909(a) of the FD&C Act authorizes FDA to issue regulations requiring tobacco product manufacturers or importers to maintain such records, make such reports, and provide such information as may be reasonably required to assure that their tobacco products are not adulterated or misbranded and to otherwise protect public health.

Under section 902(6)(A) of the FD&C Act, a tobacco product is adulterated if it is required to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i) of the FD&C Act. Under section 903(a)(6) of the FD&C Act, a tobacco product is misbranded if a notice or other information respecting it was not provided as required by section 905(j) of the FD&C Act. In addition, a tobacco product is misbranded if there is a failure or refusal to furnish any material or information required under section 909 (section 903(a)(10)(B) of the FD&C Act).

Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act, and section 704 of the FD&C Act provides FDA with general inspection authority.

V. Description of the Final Regulation and Comments and Responses

A. Introduction

We received about 100 comments to the docket for the proposed rule. In addition to the comments specific to this rulemaking that we address in this section, we received many general comments expressing support or opposition to the rule. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. In this section, we have grouped similar comments together by the topics discussed or the particular portions of the proposed rule or codified language to which they refer. To make it easier to identify comments and FDA's responses, the word "Comment," in parenthesis, appears before the comment's description, and the word, "Response," in parenthesis appears before FDA's response. Each comment is numbered to help distinguish among different comments, and the number assigned is purely for organizational purposes and does not signify value or importance. Similar comments are grouped together under the same comment number. In this section we also describe changes we made to the final rule following our consideration of the comments and other information.

As described in more detail in this section, following our consideration of these comments, we have made changes to proposed §§ 1107.10, 1107.12, 1107.18, 1107.19, 1107.22, 1107.40, 1107.44, 1107.46, 1107.48, and 1107.50. The changes are largely intended to clarify areas of confusion or address concerns raised by the comments, and we describe in detail the changes made to each of these provisions in the following paragraphs. Following our review of the comments, we are not making changes to other sections included in the proposed rule and are finalizing those sections without change. In addition, we received no comments on the proposed change to add language to § 16.1(b)(2) (21 CFR 16.1(b)(2)) regarding rescission (as included in the proposed rule), and we are finalizing § 16.1(b)(2) without change.

B. Description of General Comments and FDA Responses

(Comment 1) Some comments object to the proposed rule, stating that the rule violates the statute because the rule would not create a viable pathway to market products that qualify for the SE pathway that is more streamlined than the PMTA pathway. For example, one comment objects to the proposed rule and states that FDA has "exceeded Congressional intent by over-complicating the [premarket] pathways, ignoring the first prong of the SE standard and making the second prong nearly as burdensome as the PMTA pathway." Another comment states that regardless of whether an SE Report cites the first or second prong for determining substantial equivalence, "the SE pathway is intended to be significantly less burdensome than the PMTA pathway," and the SE pathway should "require the least information and be the simplest to implement while the PMTA pathway, with its focus on the 'protection of public health' would require the more extensive information and data." Other comments also object to the rule and state the SE pathway should be much more like a "notification" process than the PMTA pathway.

(Response 1) We disagree with these comments. We have received thousands of premarket applications, including SE Reports, and we developed this rule based on our experience with those SE Reports and the framework for substantial equivalence under sections

905(j) and 910 of the FD&C Act. The statutory requirements related to substantial equivalence differ from the statutory framework and requirements for a PMTA, and each pathway has different standards for authorization. The rule will provide applicants with additional clarity and understanding of the information needed in an SE Report for FDA to make a determination under the statutory requirements related to substantial equivalence (sections 905(j) and 910(a) of the FD&C Act). Notably, under the SE pathway, the applicant must receive an order prior to marketing the new tobacco product (unless it has received authorization through a different premarket pathway or it is a provisional tobacco product); the FD&C Act does not authorize a "notification process" as an alternative to receiving an SE order. As appropriate, however, we have developed mechanisms to lessen the burden for submitting data that are more streamlined by allowing for certifications when the data between the new and predicate tobacco products are identical (see, e.g., § 1107.18(*l*)).

(Comment 2) Some comments suggest FDA adopt an approach similar to the substantial equivalence process FDA applies to devices under sections 510(k) and 513(i) of the FD&C Act (21 U.S.C. 360(k) and 360c(i)), for example, by permitting a notification process. Other comments reference guidance documents related to the 510(k) process for devices as examples of how to implement the SE pathway for tobacco products.

(Response 2) We disagree with these comments. FDA's interpretation of SE with respect to medical devices is based on different statutory sections from those applicable to tobacco products and, due to the differences in the statutory provisions underlying the 510(k) premarket pathway, it has limited utility as a model in considering SE for tobacco products. As described in the preceding response and also in section IV below, sections 905(j) and 910(a) of the FD&C Act set out the substantial equivalence provisions that are specifically applicable to tobacco products, and reflect the differences in these regulated products. For example, the medical device provisions involve considerations related to the safety and effectiveness of medical devices. In comparison, the statutory provisions relating to SE for tobacco products focus on the

characteristics of the new tobacco product, and where there are differences, whether such differences cause the new tobacco product to raise different questions of public health.

(Comment 3) Some comments object that the proposed rule would require behavioral information in an SE Report that the FD&C Act requires only for a new product subject to a PMTA. One comment notes that because the "SE process is an exception to PMTA requirements, designed to determine whether the product should have to undergo the full PMTA process, [r]equiring manufacturers to submit PMTA-level evidence … is illogical."

(Response 3) We disagree with the suggestion that behavioral information, such as initiation and cessation information, can never be relevant in the evaluation of an SE report. Congress broadly delegated to FDA the authority to specify what should be included in an SE Report and imposed no constraints of the type the comments suggest. (See section 905 (j)(1) of the FD&C Act ("report to the Secretary [of Health and Human Services] (in such form and manner as the Secretary shall prescribe)")). As many comments point out, where the new tobacco product has different characteristics than the predicate tobacco product, the information submitted in the SE application must "contain information, including clinical data if deemed necessary by [FDA], that demonstrates… [that] the product does not raise different questions of public health." (Section 910(a)(3)(A)(ii) of the FD&C Act.) Congress included findings in the Tobacco Control Act that make clear that one of the public health purposes of the legislation was to reduce dependence on tobacco. For example, Congress stated that the Tobacco Control Act's "purposes" include ensuring that FDA has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco and promoting cessation to reduce disease risk and the social-costs associated with tobacco-related diseases. (see Tobacco Control Act sections 3(2) and (9)). In addition, Congress defined substantial equivalence to mean that the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of

public health. (See FD&C Act 910(a)(3)(A)(ii).) The reference to "this section" is a reference to the PMTA pathway. Because one of the bases for FDA finding that a product is appropriate for the protection of public health (i.e., the PMTA "standard") includes the increased or decreased likelihood that existing users will stop using and new users will initiate use of such products, it is reasonable to examine those same considerations under the SE standard to determine whether the differences between the predicate and the new product show that the product should be reviewed under the PMTA pathway.

As a result, in determining whether a new tobacco product raises different questions of public health, FDA considers potential impacts on initiation and cessation of tobacco use. If the SE Report lacks this information, then we may be unable to determine that the product is substantially equivalent.

(Comment 4) A number of comments assert that the proposed regulation does not provide enough specificity to adequately guide industry. For example, one comment states that the proposed rule lacked clarity regarding the scope, type, and amount of testing and other information needed in SE Reports for smokeless tobacco products and the comment requests that FDA include more specific requirements regarding the content of SE Reports for smokeless tobacco products. Other comments suggest the rule requires too much information or the wrong information.

(Response 4) We disagree with these comments. The rule provides content and format information that will be applicable across a range of categories and subcategories of tobacco products, including smokeless tobacco products (see, e.g., § 1107.19). In addition, after reviewing the comments received in response to our invitation to comment on design parameters for cigars, Electronic Nicotine Delivery Systems (ENDS), and other tobacco products, the final rule now includes design parameter information for these products. Based on our experience, we believe that the requirements in this rule are necessary for FDA to determine whether a product is substantially equivalent.

(Comment 5) One comment suggests that FDA should apply the rule to currently pending SE Reports.

(Response 5) As the proposed rule explained, the requirements included in the rule apply only after the effective date of this rule. Accordingly, the requirements do not apply to an SE Report for a provisional tobacco product or to any SE Report submitted before the effective date of this rule. This does not prevent applicants with pending SE Reports or those preparing SE Reports from referring to this rule for guidance on how to submit amendments to pending SE reports or prepare their SE Report prior to the effective date of this rule.

(Comment 6) At least one comment suggests that FDA revise or withdraw SE-related guidance documents when the Agency issues the final SE regulation to reduce confusion and because the guidance documents would no longer be warranted. Other comments suggest that FDA issue new guidance, including guidance documents with decision trees (e.g., similar to 510(k) process for devices).

(Response 6) FDA agrees that revision or withdrawal of guidance documents is appropriate if the recommendations are no longer relevant or could be confusing. Following issuance of this final rule, we intend to review SE-related guidance documents to determine whether to revise or withdraw any guidance documents. Similarly, we will consider whether new guidance documents should be developed or whether updates should be made to existing guidance documents.

C. Comments on Subpart B--General and FDA Responses

1. Scope (§ 1107.10)

This part establishes the procedures and provides information for the submission of an SE Report under sections 905 and 910 of the FD&C Act, the basic criteria for establishing substantial equivalence, and the general procedures FDA intends to follow when evaluating SE Reports. We are finalizing § 1107.10 (Scope) with one change from the proposed rule to reflect that this part applies to new tobacco products "other than 'premium' cigars as defined in §

1107.12." In the following paragraphs, we discuss the comments related to this section, including comments on the scope of products covered.

(Comment 7) Several comments on the proposed rule discuss "premium" cigars. These comments included requests that FDA exempt "premium" cigars from premarket requirements, create a different premarket pathway for "premium" cigars, or delay the effective date for submitting premarket applications for "premium" cigars. Other comments flag concerns with specific requirements included in the proposed rule, such as concerns related to co-packaging requirements (the comments state that "premium" cigar packaging does not have the potential to alter or affect the performance, composition, constituent, or other physical characteristics of the product); concerns related to the applicability of "product quantity" change for "premium" cigars as these are sold individually; and concerns related to the "significant natural and inherent variability" in handmade "premium" cigar products (the comments state these products cannot be manufactured by hand consistently enough to permit manufacturers to "fully characterize" them in any meaningful way to permit a traditional SE comparison). Other comments raise issues related to the applicability of proposed requirements in § 1107.19 to "premium" cigars, such as the proposed requirement that information on "[t]he type of tobacco, including grade and variety" be submitted in an SE Report, that harmful and potentially harmful constituents (HPHC) data be submitted, given the variety of cigars and lack of smoke testing methodologies for "premium" cigars, costs of HPHC testing, and insufficient lab capacity, or that stability information be provided given the characteristics of the product. Many of these comments describe differences between "premium" cigars and other cigars, e.g., mechanized versus handmade processes, and state that these differences make it more difficult for "premium" cigars to comply with SE requirements.

(Response 7) FDA received a range of comments related to "premium" cigars.[2] A recent court decision, *Cigar Ass'n of Am., et al. v. Food and Drug Admin., et al.*, "remand[ed] the [deeming final rule] to the FDA to consider developing a streamlined substantial equivalence process for premium cigars" and "enjoin[ed] the FDA from enforcing the premarket review requirements against premium cigars . . . until the agency has completed its review."[3] Under the terms of the court's order, a "premium" cigar is defined as a cigar that meets all of the following eight criteria:

1. is wrapped in whole tobacco leaf;
2. contains a 100 percent leaf tobacco binder;
3. contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar);
4. is handmade or hand rolled[4];
5. has no filter, nontobacco tip, or nontobacco mouthpiece;
6. does not have a characterizing flavor other than tobacco;
7. contains only tobacco, water, and vegetable gum with no other ingredients or additives; and
8. weighs more than 6 pounds per 1,000 units.

As directed by the court in the *Cigar Ass'n of Am.* decision, FDA is further considering the comments submitted to the deeming rule docket that requested FDA create a streamlined SE process for "premium" cigars. Additionally, FDA intends to undertake a research effort specific to "premium" cigars (as defined in the preceding paragraph) and their health effects, patterns of

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[2] Cigars are subject to Chapter IX of the FD&C Act as a result of regulations enacted by FDA (Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 FR 28974, May 10, 2016 ("deeming final rule")). The deeming final rule extended FDA's regulatory authority to all tobacco products (excluding accessories of such products). These products include all cigars, pipe tobacco, waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other novel tobacco products.

[3] *Cigar Ass'n of Am., et al. v. Food and Drug Admin., et al.*, Case No. 1:16-cv-01460 (APM), (D.D.C. Aug. 19, 2020), Dkt. No. 214 (*Cigar Ass'n of Am.*).

[4] A product is "handmade or hand rolled" if no machinery was used apart from simple tools, such as a scissors to cut the tobacco prior to rolling.

use (such as frequency of use and usage patterns among underage persons), and other factors. The results of this research will inform the Agency's regulatory policy with respect to premarket review of "premium" cigars.

Because these are ongoing efforts, at this time, FDA is not finalizing the proposed SE rule with respect to "premium" cigars. Rather, FDA will take appropriate action once it has further considered the comments submitted to the deeming rule docket that suggested FDA create a streamlined SE process for "premium" cigars, as well as the results from its research. As such, the codified language has been revised to exclude "premium" cigars from the scope of this final rule, and the *Cigar Ass'n of Am.* court's definition of "premium" cigars has been added to § 1107.12.

(Comment 8) One comment suggests that FDA add a definition for pipe tobacco and create a different SE premarket pathway for pipe tobacco, for example, more aligned with the 510(k) process for medical devices.

(Response 8) We interpret this comment to be a request that FDA consider streamlined options within the three premarket pathways available to pipe tobacco seeking authorization: PMTA, SE, and exemption from SE, as provided in sections 905 and 910 of the FD&C Act. Generally speaking, within the construct of the SE premarket pathway, there are options for more streamlined submissions, that will still provide the agency with the information we need to determine whether the new tobacco product is SE, which this final rule reflects. For example, where appropriate, certain requirements (e.g., design parameters) are tailored by type of product. In addition, the rule generally provides options to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco product (§ 1107.18(*l*)). This option may be helpful to applicants as a means of minimizing the content to be submitted, when appropriate. Finally, because we are still considering how best to define "pipe" tobacco, we are not including a definition of the term, but intend to undertake further actions to

define the term, if needed, at a future time. However, we do not think a formal definition of "pipe" tobacco is needed to continue regulating the product or to conduct an SE review.

(Comment 9) Some comments request that FDA clarify which changes may proceed through the SE exemption pathway and those which may not. The comment requests that FDA define the term "minor modification" to help manufacturers understand which changes would qualify for the SE exemption pathway. For example, the comments request that changes to maintain product consistency or changes made by suppliers to components be considered as changes eligible for the SE exemption pathway.

(Response 9) Requests for information on which changes would qualify under the SE exemption pathway or for further information on the term "minor modification," relate to 21 CFR 1107.1 (see https://www.federalregister.gov/documents/2011/07/05/2011-16766/tobacco-products-exemptions-from-substantial-equivalence-requirements). Please note that additional information related to exemption requests may be found at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence; FDA also maintains information on exemption requests that FDA has granted at: https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se.

2. Definitions (§ 1107.12)

Proposed § 1107.12 listed terms and definitions used in the proposed rule. In this final rule, we have added a definition of "premium" cigars, as well as updated several definitions on our own initiative to clarify the meaning or to reflect current premarket review processes or to help the definitions apply across product categories.

As discussed in section V.C.1 of this final rule, we are adding the *Cigar Ass'n of Am.* court's definition of "premium" cigars to § 1107.12. That definition is:

- "*Premium*" cigars means a type of cigar that: (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by

weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7) contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units.

The updates to § 1107.12 are to the following terms:

- *Brand* to add an "s" following "brand name" in the definition;
- *Constituent* to add "(e.g., smoke, aerosol, droplets)," to delete "or any chemical or chemical compound in mainstream or sidestream tobacco smoke," to add "or part" following component, and to replace "smoke" with "emission";
- *Finished tobacco product* to move "separately" to follow "consumers" and to add "or in the final form in which it is intended to be sold to consumers" to better clarify what is meant by finished;
- *Harmful and potentially harmful constituent* to add the phrase "including as an aerosol or any other emission" in paragraph (1);
- *Heating source* to change "a" to "the";
- *Other features* to delete "and are necessary for review"; and
- *Submission tracking number* to add "voluntary" and to more closely track the statutory language by substituting "that a tobacco product was commercially marketed in the United States as of February 15, 2007" for "grandfathered."

We also received comments on several definitions included in the proposed rule, and we describe and respond to those comments in the following paragraphs. Following consideration of these comments, we have added a definition of "commercially marketed." In addition, we have made changes to the definition of commercial distribution and predicate tobacco product, as well as removing the definition "grandfathered tobacco product," as discussed in the following

paragraphs related to those terms. Please note that if there were no comments on a definition included in the proposed rule, there is no discussion related to that definition. We are finalizing all other definitions without change from the proposed rule.

- *Accessory*

(Comment 10) One comment supports the definition of accessory, noting that it reflects the definition included in the deeming final rule.

(Response 10) We agree and note the final rule includes this definition without change from the proposed rule.

- *Commercial distribution*

We proposed to define commercial distribution as: to mean any distribution of a tobacco product to consumers or to another person through sale or otherwise, but does not include interplant transfers of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale. "Commercial distribution" does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption. For foreign establishments, the term "commercial distribution" has the same meaning, except that it does not include distribution of a tobacco product that is neither imported nor offered for import into the United States.

In the following paragraphs, we discuss comments we received on the proposed definition of commercial distribution. After considering the comments related to this proposed definition, we have made several changes to this definition that are included in the final rule. Specifically, we are: (1) adding "whether domestic or imported" to clarify the distribution, (2) changing "another," to "any," (3) deleting "through sale or otherwise" as unnecessary; (4) deleting "registered" as a modifier to "establishment," (5) adding "personal" as a modifier to "consumption," and (6) striking some of the language related to what commercial distribution does not include as other changes to the definition now clarify this point.

(Comment 11) One comment states that the definition of commercial distribution included in the proposed rule is overly broad and unworkable. This comment notes that including the phrase "any distribution of a tobacco product to consumers *or to another person* through sale or *otherwise*" (emphasis in comment) renders the definition open-ended and potentially includes any movement of a finished product that does not fit within one of the enumerated exclusions, even if the product is not available for consumption or resale. The comment notes that if FDA is concerned with distribution of tobacco products that may be used for sampling purposes, then FDA should tailor the definition to specify sampling (or to an activity that either is a sale or promotes the sale of a product).

(Response 11) FDA agrees that the definition of commercial distribution included in the proposed rule required additional refinement. We have thus removed "through sale or otherwise" from the definition to clarify that commercial distribution is not limited to the sale of tobacco products to the consumer. However, "any person" is necessary to capture movement such as that between a manufacturer, importer, and distributor. As described in the preceding paragraph, however, FDA has made minor revisions to the definition for clarification to help in understanding the scope of this term.

(Comment 12) At least one comment objects to the use of "registered" establishments in the definition of commercial distribution, stating that FDA should not require that interplant transfers be between registered establishments to be excluded from the scope of commercial distribution. This comment also notes that because only domestic establishments are currently required to register, interplant transfers with a company's foreign manufacturing facilities (that are not registered) would be considered commercial distribution under the proposed definition.

(Response 12) We agree that "registered" should be deleted, and we have updated the definition in this final rule to reflect this deletion. Furthermore, as we previously noted in the proposed rule, the term commercial distribution excludes the providing of a tobacco product for product testing where such products are not made available for personal consumption or resale.

Additionally, FDA does not intend this term to include the handing or transfer of a tobacco product from one consumer to another for personal consumption (consumer to consumer transfers).

(Comment 13) One comment requests that FDA use the same definition for commercial distribution and commercial marketing and proposes that the definition be revised to recognize that commercial marketing and commercial distribution may occur from the time of sale from a foreign manufacturer to a U.S. distributor. The comment suggests that this approach would better reflect that many pipe tobaccos are sold as private label items to a specific retailer with a limited geographical footprint.

(Response 13) We decline to make a change to combine these definitions because, although the terms have some overlap, they are also distinct, as reflected in the statute. Thus, it would not be appropriate to combine the terms. As we discuss in the paragraphs related to the definition of "new tobacco product," following our review of comments, we have decided to include a definition of commercially marketed in this final rule. In response to the comment related to pipe tobacco sales, we note that with respect to the sale from a foreign manufacturer to a U.S. distributor, the final rule's definitions of commercially marketed and commercial distribution include a sale from a foreign manufacturer to a U.S. distributor and sale of tobacco products to a specific retailer with a limited geographical footprint. Applicants or others who have questions as to whether a specific activity falls within these terms should contact FDA.

- *Component or part*

We proposed to define component or part as "any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product." In the following paragraphs, we summarize the comments we received on this proposed definition of component and part, which we are finalizing without change. We also

received comments on the inclusion of "container closure system" as a subset of component or part, and we address those comments in the paragraphs related to the definition of container closure system.

(Comment 14) Some comments express concern about the definition of component and part noting, for example, that using the terms interchangeably can be confusing and that FDA should either define each separately or settle on one term and use that term. Another comment supports the definition of component and part noting that the term and definition are consistent with language in the deeming final rule.

(Response 14) We agree that it is appropriate in this context to remain consistent in defining terms across tobacco product regulations. Thus, this final rule maintains the definition that was included in the proposed rule and which reflects the definition included in the deeming final rule (see, e.g., 21 CFR 1100.3). We disagree with comments suggesting the definition is too broad or that we should break "component or part" into two definitions at this time. Although we appreciate the concern about confusion, the rule makes clear that both component and part share the same definition, and applicants can apply the terms accordingly. Should FDA determine at some future point that a distinction between the terms is necessary, we would undertake notice and comment rulemaking on the issue before we would apply any changes.

(Comment 15) One comment requests that FDA exercise enforcement discretion for the submission of SE Reports for smoking pipes. The comment acknowledges that the deeming final rule states that smoking pipes are components and parts of tobacco products (81 FR 28974 at 29042) but notes that FDA has exercised enforcement discretion for the submission of ingredient reports for smoking pipes and suggests FDA do the same for SE requirements.

(Response 15) As the comment states, FDA has established compliance policies related to other FD&C Act requirements for smoking pipes. We decline to extend or establish such a premarket compliance policy for smoking pipes because pipes can impact the risk profile of the tobacco product with which the pipe is used, e.g., by increasing HPHC exposure. We note that

the rule includes options to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco product (§ 1107.18(*l*)). This option may be helpful to applicants as a means of minimizing the content to be submitted, when appropriate. We also encourage potential applicants to reach out to FDA to discuss questions related to preparing an SE Report.

- *Container Closure System (CCS)*

We proposed to define "container closure system" as "any packaging materials that are a component or part of a tobacco product." As described in the following paragraphs, we received several comments related to the definition of container closure system included in the proposed rule, as well as comments on the discussion of co-packaging that was included in the proposed rule. After considering the comments, we are finalizing this definition without change from the proposed rule.

(Comment 16) Some comments object to the definition of container closure system as "any packaging materials that are a component or part of a tobacco product," stating it is inconsistent with the FD&C Act (as amended by the Tobacco Control Act) and "an impermissible back door effort" to subject packaging changes to SE review. One comment adds that the definition transforms packaging into a "component or part" of a tobacco product contrary to a D.C. District Court decision (*Philip Morris USA Inc.* v. *FDA*, 202 F. Supp 3d 31 (D.D.C. 2016)) (*Philip Morris* decision). These comments also state that although the FD&C Act provides FDA with authority to regulate packaging under sections 903(a) and 905(i) of the FD&C Act, that authority does not provide FDA with the ability to include packaging under the definition of component or part and thereby subject packaging to premarket review.

(Response 16) FDA is not requiring that an applicant include information on all aspects of the packaging, but the requirements of the final rule do require information on the CCS as a component or part of the tobacco product. As explained in the proposed rule, a container closure system is a component or part of a tobacco product because of its potential to alter or affect the

performance, composition, constituents, or other physical characteristics of the product. We are including this requirement in the final rule because, as discussed in the proposed rule, treating this distinct subset of packaging as a component or part furthers the fundamental purpose of the Tobacco Control Act to protect the public health. Some examples include CCS where substances in the CCS are intended or reasonably expected to affect product moisture, or when menthol is applied to inner foil to become incorporated into the consumed product (Ref. 1). FDA can require the applicant to demonstrate that the change in the container closure system does not cause the new tobacco product to raise different questions of public health where such information is needed to demonstrate substantial equivalence.

(Comment 17) Other comments assert that the definition of container closure system and the preamble discussion in the proposed rule improperly provide that a container closure system "is" considered a component or part "categorically, without regard to whether the container closure system somehow changes the tobacco product in any way." The comments contend this approach is also contrary to the *Philip Morris* decision and that the plain meaning of component and part "pertains to something that is or can be expected to become incorporated into the tobacco product itself, meaning a piece or portion of a larger whole tobacco product." The comments state that container closure systems are not components or parts because the package is external to the tobacco product. The comments disagree with the examples that FDA included in the preamble to the proposed rule, such as the soft pack for cigarettes, stating these are examples of packaging that are outside the scope of components and parts.

(Response 17) As described in detail in the proposed rule, FDA defines "component or part" as any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Packaging that constitutes the container closure system is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product (e.g., leaching substances that

are then incorporated into a tobacco product), and is thus a component or part of a tobacco product. Where a change in the container closure system could affect the chemistry of the product, FDA could require the applicant to demonstrate that the change in the container closure system does not cause the new tobacco product to raise different questions of public health.

Packaging that is not the container closure system is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product and is therefore not a component or part of a tobacco product. As such, packaging that is, for example, the box around a blister pack, is not a CCS if it is not intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of the tobacco product within the blister pack.

For example, packaging materials constitute a container closure system if substances within that packaging are intended or reasonably expected to affect product moisture, e.g., when the manufacturer changes the package of a moist snuff from plastic to fiberboard, which can affect microbial stability and tobacco-specific nitrosamine (TSNA) formation during storage. Another example of this is when menthol or other ingredients are applied to the inner foil to become incorporated into the consumed product (Ref. 1). Packaging materials may also be intended or reasonably expected to affect the characteristics of a tobacco product by impacting the rate of leaching into, and ultimately, the amount of substances found in, the consumable tobacco product. In fact, it has been demonstrated that compounds in packaging materials may also diffuse into snuff and affect its characteristics (Ref. 2). Thus, for example, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system (e.g., a plastic versus a metal container of smokeless tobacco). A difference in tobacco moisture is reasonably expected to affect microbial growth in the product, extraction efficiency, and total exposure to nicotine or the carcinogens N-nitrosonornicotine (NNN) or 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (Ref. 3).

Considering a distinct subset of packaging (i.e., container closure system) to be a component or part is consistent with the FD&C Act and furthers the fundamental purpose of the Tobacco Control Act to protect the public health. For example, section 900(1) of the FD&C Act (21 U.S.C. 387(1)) defines an "additive" as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substance intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical. Congress specifically included a broad definition of additive that encompasses not just substances that do in fact have such effects but also may reasonably be expected to. Similarly, if FDA were to adopt a narrow construction of "tobacco product" to exclude these materials, the Agency's ability to evaluate whether the differences between the new and predicate tobacco product cause the new tobacco product to raise different questions of public health would be impeded, thereby leaving the Agency unable to fully execute its mission to protect the public health. The definition of "package" in section 900(13) of the FD&C Act does not dictate a contrary result, and can be reasonably interpreted to mean that a distinct subset of packaging is also a component or part of a tobacco product.

Contrary to one of the comments, the court's decision in *Philip Morris* does not necessitate a different interpretation than the one FDA has adopted and described above. First, the court was presented with a challenge relating to FDA's regulation of product labels and changes in product quantities. It was not asked to decide on--and the Agency did not brief--the validity of FDA's interpretation of container closure system. Second, FDA is not seeking to incorporate into the SE evaluation any packaging that is not intended nor reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the product itself. As noted above, for example, the packaging around a blister pack is not part of the SE review

process if it is not intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of the tobacco product within the blister pack. The court's opinion in *Philip Morris* emphasizes the importance of looking to whether the "physical attributes of the product itself" have changed in determining whether a tobacco product is new. *Philip Morris*, 202 F.Supp. 3d at 51. By limiting our review to changes to the CCS, we are only looking at packaging that is intended or reasonably expected to affect or alter the performance composition, constituents, or characteristics of the tobacco product--in other words, we are looking at changes that could affect the "physical attributes" of the product. Such an interpretation is consistent with the *Philip Morris* decision, and, as explained above, consistent with the Tobacco Control Act's purpose and treatment of other definitions within the FD&C Act.

(Comment 18) One comment states that a container closure system should only qualify as a component or part of the product when it is designed or reasonably expected to change the characteristics of the tobacco product, and not when it is designed to maintain or preserve the characteristics of the product. Other comments state that FDA should not require an SE Report for a change to a CCS because a product's packaging does not impact its characteristics.

(Response 18) If aspects of packaging of a tobacco product are intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product, we consider that packaging to be a CCS that is a component or part of the product. A change to the CCS would require a premarket submission. Packaging that is intended or reasonably expected to maintain or preserve the characteristics of the product could be reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the product. For example, as described in the preceding response, packaging material that affects the characteristics of a tobacco product, including cigars, by impacting the moisture level or shelf life of a tobacco product is a container closure system (e.g., a plastic versus a metal container of smokeless tobacco) (Refs. 1-3).

(Comment 19) Some comments object to the discussion in the proposed rule that stated that "co-packaging two or more tobacco products within the same container closure system results in a new tobacco product." The comments assert that this "new category of packaging" created by the proposed rule has no basis in the FD&C Act and that it is improper to regulate co-packaged tobacco products as part of SE review. Accordingly, the comments request FDA to exclude co-packaged tobacco products from the scope of new tobacco products. The comment argues that as long as each separate product is legally marketed, co-packaging of the products does not create a new tobacco product requiring SE review. Other comments state that changes to the container closure system of co-packaged products should only result in a new product when they intend or reasonably expect to change the physical characteristics of the product.

(Response 19) We agree that changing the packaging of co-packaged tobacco products only results in a new tobacco product where such packaging is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product. Under section 910(a)(1)(B) of the FD&C Act, new tobacco products include those that are new because they have been rendered new through any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. Therefore, if two or more products are proposed to be co-packaged together within a single container closure system, that results in a new tobacco product requiring premarket authorization. However, as explained in the proposed rule, co-packaging two or more legally marketed tobacco products, where there are no changes, including no change to the container closure system(s), does not result in a new tobacco product.

- *"Grandfathered" tobacco product*

We proposed to include a definition of "grandfathered tobacco product" as "a tobacco product that was commercially marketed in the United States as of February 15, 2007, and does

not include a tobacco product exclusively in test markets as of that date." Such a product would not be subject to the premarket requirements of section 910 of the FD&C Act. We received several comments on this definition, as well as related comments on the definition of new tobacco product, and we respond to those comments in the following paragraphs and in the paragraphs related to "new tobacco product." We are removing this definition because the term is no longer used in the codified text. In this preamble, we have changed the term from "grandfathered tobacco product" to "Pre-Existing tobacco product" because it more appropriately describes these products, by using the more precise "Pre-Existing" in place of "grandfathered." FDA received several comments regarding the definition of "Pre-Existing tobacco product,"[5] which are discussed as follows.

(Comment 20) Several comments suggest that we consider alternative dates to February 15, 2007, as the date after which premarket review would be required for deemed tobacco products, such as the effective date of the deeming final rule (i.e., August 8, 2016).

(Response 20) As indicated in the deeming final rule, FDA lacks the authority to change the February 15, 2007, date for any tobacco products, including deemed tobacco products.[6] This date is explicitly prescribed in the statute. Section 910(a)(1)(A) of the FD&C Act states, in pertinent part, that the term "new tobacco product" means, in part, any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007. For purposes of the SE pathway, the statute also clearly states that a predicate product must be commercially marketed (other than for test marketing) in the United States on February 15, 2007, in both section 910(a)(2)(A) and section 905(j)(1) of the FD&C Act.

- *Harmful and Potentially Harmful Constituent (HPHC)*

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[5] While comments were submitted regarding the term "grandfathered tobacco product," we describe them using the new term, "Pre-Existing tobacco product," throughout this document for the sake of clarity.
[6] Note that for the purposes of this final rule, "deemed tobacco products" are those tobacco products subject to the deeming final rule.

We proposed to define "harmful and potentially harmful constituent" as any chemical or chemical compound in a tobacco product or tobacco smoke or emission that: (1) is or potentially is inhaled, ingested, or absorbed into the body and (2) causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products. We received comment on this definition, which we respond to in the following paragraphs. We are finalizing this definition to clarify that HPHCs include chemicals or chemical compounds that are potentially inhaled, ingested, or absorbed into the body "as an aerosol or any other emission" as described in the preamble to the proposed rule.

(Comment 21) At least one comment supports the proposed definition, noting it is consistent with the criteria applied in formulating the HPHC list and includes both substances that are or potentially could be inhaled, ingested, or absorbed into the body (77 FR 20034, April 3, 2012).

(Response 21) We agree with the comment and note the definition is included in the final rule, with the change as noted, which we made to ensure consistency with other regulatory documents.

- *Ingredient*

We proposed to define "ingredient" as tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing. We received a comment on this definition, which we respond to in the following paragraph. We are finalizing this definition without change.

(Comment 22) One comment disagrees with the proposed definition of "ingredient," stating that "compounds reasonably expected to be formed through a chemical reaction during manufacturing are not properly identified as ingredients" and that the proposed definition "is imprecise" and will "inevitably be subject to varying interpretations."

(Response 22) We disagree that this definition should not include "compounds reasonably expected to be formed through a chemical reaction" as information on these ingredients is needed to aid FDA in making an SE determination. However, we note that the phrase "compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing" should be interpreted as compounds formed through well-known chemical reactions, for example, reactions of sugars which could lead to the formation of related alcohols, ketones, aldehydes, and esters (Refs. 4 and 5) and reactions of nicotine which could lead to the formation of related N-nitrosamines (Ref. 6).

- *New tobacco product*

In the proposed rule, we included the statutory definition of "new tobacco product," which is defined as: (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. (See section 910(a)(1) of the FD&C Act.) The final rule continues to include this statutory definition. In the following paragraphs, we respond to comments related to the definition of "new tobacco product" generally.

In addition, FDA received many comments related to our invitation to comment on the terms "test marketing" and "commercially marketed," which are terms included in the statutory definition of new tobacco product. In subsequent paragraphs, we describe and respond to these comments on test marketing and commercially marketed. Following our consideration of these comments, we are adding a definition of "commercially marketed," to the final rule, which states "commercially marketed means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States." We also describe this definition below.

(Comment 23) One comment requests that FDA clarify that, under the definition of new tobacco product, a modification to an existing product's label does not require an SE Report. This comment cites the *Philip Morris* decision.

(Response 23) A modification to an existing product's label standing alone does not require an SE Report.

(Comment 24) Some comments address FDA's interpretation that a tobacco product exclusively test marketed as of February 15, 2007, is considered a new tobacco product under section 910 of the FD&C Act. Other comments indicate FDA's interpretation is correct, and one of these comments also notes that a tobacco product that was test marketed as of February 15, 2007, cannot serve as a predicate tobacco product under section 905(j) of the FD&C Act.

(Response 24) Following our consideration of these comments, we agree with the comment indicating that a tobacco product test marketed in the United States as of February 15, 2007, is not a new tobacco product. Section 910(a)(1)(A) defines a "new tobacco product" to include "any tobacco product (including those in test markets) that was not commercially marketed in the United States as of February 15, 2007." The parenthetical "including those in test markets" in section 910(a)(1)(A) of the FD&C Act modifies the phrase directly before it--"any tobacco product"--and is intended to clarify that tobacco products commercially marketed in test markets in the United States as of February 15, 2007, should be treated the same way as any other tobacco product that was commercially marketed as of February 15, 2007, i.e., they are not "new tobacco products." We also agree with the comment that states that under section 905(j) of the FD&C Act, a tobacco product that was solely in a test market as of February 15, 2007, despite being a Pre-Existing tobacco product, cannot serve as a predicate tobacco product, which is consistent with the position taken in the proposed rule. Section 905(j)(1)(A)(i) describes products that can serve as valid predicate tobacco products: a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that the Secretary by delegation to FDA has previously determined, pursuant to

subsection (a)(3) of section 910, is substantially equivalent. Here, the parenthetical "other than for test marketing" explains a product solely sold in test markets as of February 15, 2007, cannot serve as a valid predicate tobacco product. Therefore, a product cannot serve as a predicate if it was exclusively sold in a test market as of February 15, 2007.

(Comment 25) Another comment disagrees with FDA's interpretation that the phrase "as of" means "on" arguing that "[i]f Congress has intended that [Pre-Existing tobacco] products must have been commercially marketed on the singular date of February 15, 2007, it would have used the word 'on' in the statute," but, instead, "Congress used the phrase 'as of,' which, in this context, plainly communicates marketing on or before February 15, 2007" (emphases omitted). This comment references a dictionary definition of "as of now" as meaning up to the present time and also notes that Congress used the term "on" in other places in the Tobacco Control Act (e.g., section 904(c)(1) use of "on June 22, 2009"). The comment argues that "as of" should be interpreted as "on or before."

(Response 25) As discussed in the proposed rule, FDA's longstanding interpretation is that "as of" means that the tobacco product was commercially marketed in the United States "on February 15, 2007" (see the final guidance entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" (79 FR 58358, September 29, 2014)). Contrary to the comment, the term "as of" does not have a plain meaning. The dictionary definitions of "as of" include: "on; at" (Webster's II New Riverside University Dictionary, 1988); "beginning on; on and after" (Webster's Unabridged Dictionary Random House 1997); "from, at, or until a given time" (The American Heritage Dictionary of Idioms 2003); "on, at, from--used to indicate a time or date at which something begins or ends" (Merriam Webster's Online Dictionary). As evidenced from these varying definitions, the term is ambiguous. "[A]s of" could be interpreted either as "at any time prior to and not necessarily including on the particular date" (in short referred to as the "on or before" interpretation) or as "at any time up to and necessarily including on the particular date" (in short referred to as the

"on" interpretation). Interpreting "as of" to mean "on" gives a firm line of demarcation that provides clarity. Additionally, reading "as of" to mean "on or before" would mean that obsolete, abandoned, or discontinued tobacco products could return to the market without any premarket review and could serve as predicates under the substantial equivalence provision. It is reasonable to conclude that Congress did not intend to allow an immeasurable number of obsolete, abandoned, or discontinued tobacco products that were marketed before February 15, 2007, to return to the market without any premarket review or serve as predicates under the substantial equivalence provision, but rather intended to confine this number to those tobacco products that were commercially marketed in the United States on February 15, 2007. Thus, we decline to change to the interpretation the comment suggests.

- *Test marketing and commercially marketed*

In the preamble to the proposed rule, we explained that FDA was considering whether to add the following definition of test marketing: "test marketing" means distributing or offering for sale (which may be shown by advertisements, etc.) a tobacco product in the United States for the purpose of determining consumer response or other consumer reaction to the tobacco product, with or without the user knowing it is a test product, in which any of the following criteria apply: (1) offered in a limited number of regions; (2) offered for a limited time; or (3) offered to a chosen set of the population or specific demographic group. In addition, the proposed rule stated we were considering whether to add a definition of commercially marketed, such as "offering a tobacco product for sale to consumers in all or in parts of the United States."

After reviewing the comments we received in response to the invitation to comment, we have determined that further discussion of the scope of "test marketing" is needed before we issue a definition of this term; however, following our consideration of comments, we have decided to codify a definition of "commercially marketed." The proposed rule stated we were considering whether to add a definition of commercially marketed, such as "offering a tobacco product for sale to consumers in all or in parts of the United States." The final rule now includes

a definition of "commercially marketed" as selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States. This addition clarifies that tobacco products that are not sold or offered for sale in order to reach consumers within the United States, such as tobacco products sold solely for export fall outside of the definition of commercial marketing.

We describe the comments and our responses on these terms in the following paragraphs.

(Comment 26) Several comments provide suggestions on how to define commercially marketed and test marketed, and some comments request that FDA not define these at all, finding the discussion in the proposed rule confusing. One comment suggests that FDA define "commercially marketed" and "test marketing" as meaning the same thing. Those comments addressing test marketing indicate that manufacturers may distribute and market tobacco product in limited regions for a set period of time without test marketing the products. Some comments suggest that "test marketing" should not be based on time or geographical region, but rather should be based on manufacturer intent. One comment suggests that consumer response is an inherent part of marketing any product, for testing purposes or otherwise.

Comments addressing the term "commercially marketed" as discussed in the proposed rule, suggest that if defined, it should be defined as "offered for sale in the United States to any individual or entity by advertising or by any other manner used to communicate that the tobacco product is available for purchase." One comment states FDA has never required firms to demonstrate that a product was offered for sale to consumers, and, in fact, many manufacturers do not market or sell directly to consumers, to establish that their tobacco product is a Pre-Existing tobacco product. Other comments suggest either that a product sold wholly within one state would be commercially marketed or that anything other than a nationwide product launch could constitute test marketing.

(Response 26) Following our consideration of the responses to the proposed rule's invitation to comment on these terms, we agree that further discussion and experience on the

term test marking is needed in order to more accurately capture the scope of this term. As we stated previously, we are accordingly not including a definition of test marketing in the final rule. However, after reviewing the comments related to commercially marketed, we have added a definition of this term to the final rule, which reflects the input we received. Specifically, we added a definition stating that "commercially marketed" means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States. Examples of products that may not be covered by the definition of commercially marketed include investigational tobacco products and free samples. Examples of documentation of commercial marketing may include dated bills of lading, dated freight bills, dated waybills, dated invoices, dated purchase orders, dated advertisements, dated catalog pages, dated promotional material, dated trade publications, dated manufacturing documents, inventory lists, or any other document demonstrating that the product was commercially marketed in the United States as of February 15, 2007.

Importantly, as we explain in a preceding response, we also note that although a "solely" test marketed product may not be considered "new" under section 910 of the FD&C Act, it cannot serve as a predicate product under section 905(j) of the FD&C Act. Test marketed products may include, for example, products that were sold or offered for sale to consumers to determine the commercial viability of a product through the collection of consumer reaction data.

(Comment 27) One comment requests that any definition of a test marketed product include an alternative pathway for the test marketed product to come to the market without having to file an SE Report. This comment proposes a "less cumbersome process by which products may be test marketed, in order that companies may develop data on shelf-life, HPHC changes, if any, over time, changes in nicotine content, etc." This comment proposes allowing the filing of a report advising FDA of a manufacturer's desire to test market a product without the manufacturer having to submit a premarket application.

(Response 27) This comment appears to provide suggestions more closely concerned with research or investigational tobacco products. Such products are outside of the scope of this rulemaking. In general, any tobacco product (including products in test markets) that was not commercially marketed in the United States as of February 15, 2007, is considered a "new tobacco product" under section 910(a)(1) of the FD&C Act. As such, manufacturers of test marketed products that were not commercially marketed in the United States as of February 15, 2007, are required to first submit to FDA a PMTA under section 910 for the new tobacco product, and FDA must issue an order authorizing the commercial distribution of the new tobacco product; or submit an SE Report under section 905(j) of the FD&C Act, and FDA must issue an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act); or FDA must find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act, before the product may be introduced into commercial distribution. If any new tobacco product, including a test marketed product, enters into interstate commerce for commercial distribution without an order or a finding of exemption from substantial equivalence, it is adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

- *Package or packaging*

We proposed to define "package or packaging" as a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers. Although there were no comments to the definition included in the proposed rule, there were comments that discussed packaging in the context of CCS. We address those comments in the discussion of the definition of CCS. We are finalizing the definition of package or packaging without change.

- *Predicate tobacco product*

We proposed to define "predicate tobacco product" as a tobacco product that is a Pre-existing Tobacco Product or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act. We received some comments related to this term, which we discuss in the following paragraphs (see also comments to § 1107.18(f) for related discussion). We are finalizing this definition with changes to more closely mirror the statutory language. Thus, the definition in the final rule states that "predicate tobacco product" means a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act.

(Comment 28) Some comments request that FDA expand the definition of predicate tobacco product to allow a product for which FDA issues a marketing order under the PMTA pathway to serve as a predicate tobacco product. Other comments suggest that tobacco products authorized through the SE exemption pathway could serve as valid predicates.

(Response 28) The FD&C Act establishes which tobacco products may serve as eligible predicate tobacco products for the SE premarket pathway. These products are limited to tobacco products that were commercially marketed (other than for test marketing) in the United States as of February 15, 2007, and products that were previously found SE by FDA. (See section 905(j)(1)(A) of the FD&C Act.)

- *Substantial equivalence*

In the proposed rule, we proposed to include the statutory definition of substantial equivalence, which states:

> Substantially equivalent or substantial equivalence means, with respect to a new tobacco product being compared to a predicate tobacco product, that FDA by order has found that the new tobacco product:
> (1) Has the same characteristics as the predicate tobacco product; or
> (2) Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to require premarket review under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health.

(See section 910(a)(3) of the FD&C Act.)

In the proposed rule, we did not propose definitions of "same characteristics" and "different characteristics" under section 910(a)(3)(A) of the FD&C Act. Rather, the proposed rule explained that FDA is considering whether the "same characteristics" prong might be appropriate for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine whether the new product raises different questions of public health. The proposed rule included four examples of changes between the new and predicate products that might be appropriate to proceed through the "same characteristics" prong, either individually or in combination, and several examples where a new product would have "different characteristics" because the new product was dissimilar enough from the predicate that FDA could not determine without scientific information whether the new tobacco product raised different questions of public health. We noted these examples were based on our current thinking, relying on the current state of science and the available evidence. We noted that, if evidence arises in a particular case that requires more information from an applicant, we would communicate to the applicant what information is needed to demonstrate that the new tobacco product is substantially equivalent. The proposed rule also included several factors that FDA might consider when determining if a new product raised different questions of public health. We invited comments on this discussion.

FDA received a number of comments related to this discussion. Following our consideration of these comments, we have further refined our thinking on these terms, particularly on changes that might be appropriate to proceed through the same characteristics prong. This includes adding other examples to this list. We describe our thinking on these updates in the following paragraphs. The final rule continues to include the statutory definition of substantial equivalence, and does not include codified definitions of "same characteristics" or "different characteristics." FDA intends to further consider the scope of these terms and will

undertake further notice and comment rulemaking before moving to further define any of these terms by regulation.

Following are examples of changes that are likely to be appropriate to proceed as same characteristics at this time:

- a change in product quantity between the new and predicate tobacco products;
- a change in container closure system between the new and predicate non-moist tobacco products (e.g., soft pack to hard pack of cigarettes);
- a change in container closure system between the new and predicate non-moist tobacco products where the same material is being used (e.g., change from one plastic container to another plastic container, change from one metal container to another metal container) and there is no difference in flavors being added to the container closure systems that would change the characterizing flavor;
- for moist tobacco products, a change in container closure system between the new and predicate tobacco products from one type of plastic to another similar type of plastic where there is no difference in flavors being added to the container closure systems that would change the characterizing flavor and no difference in size of the container closure system;
- a change to a lower amount of total tobacco in the new tobacco product without any corresponding changes in other ingredients or characteristics in the new tobacco product;
- a change in tipping paper color from plain to cork where the target specifications of the tipping paper are identical;
- a change in adhesive in the non-combusted portion of a cigarette;

- the replacement of one filter tow with an alternate filter tow with identical target specifications (e.g., vendor specifications, measured values for denier per filament, total denier);[7]
- the removal of a dye or ink from the non-combusted portion of a tobacco product or removal of printed monogram ink from the barrel of a cigarette;
- a change to replace a lower grade version of an ingredient with an equal quantity of a higher grade version of the same ingredient (e.g., replacing nicotine with USP grade nicotine);
- a change to remove a single flavor ingredient, including a complex ingredient, in the new tobacco product compared to the predicate or removing an ingredient in the predicate tobacco product and replacing that ingredient with an equal quantity of water in the new tobacco product;
- for combusted tobacco products, a change in the pattern of non-ink watermark on papers or wrappers, provided the papers or wrappers have identical target specifications and the change does not alter or affect the design parameters of the paper/wrapper;
- for combusted tobacco products, a change from one paper or wrapper to a similar paper or wrapper from an alternate supplier that do not impact HPHC yields;
- a change between a new and predicate tobacco product that results in a removal of characterizing flavor (e.g., removal of menthol from cigarettes, or removal of cherry flavor in smokeless tobacco), as well as removal of a flavor from a component of a finished tobacco product (e.g., removal of vanilla flavored adhesive in cigars and replacement with a non-flavored adhesive);
- a change in inert tip material (e.g., replacing a wood tip with a plastic tip on a cigar);

[7] Note that the addition or removal of a filter between the new and predicate tobacco products would not likely succeed through the same characteristics prong because the addition or deletion of a filter could impact product performance or HPHC yields and result in different exposures to the consumer and population.

- a change from non-Fire Standard Compliant (FSC) paper to FSC paper (also known as low ignition propensity paper);
- a change from one FSC paper to an alternate FSC paper; and
- an absolute increase or decrease in ventilation of 11 percent or less between the new and predicate tobacco product (Ref. 7).

(Comment 29) Some comments note that the *Philip Morris* decision is instructive on the meaning of the term "same characteristics." One comment discussing the district court decision in the *Philip Morris* (*Philip Morris*, 202 F.Supp. 3d at 54) case stated that "same characteristics means the product has more than minor modifications to a predicate product, but less than significant modifications". The comments state that the district court rejected FDA's interpretation that same characteristics meant that the new and predicate products had identical characteristics. Other comments note the language in the decision stating that "the 'same characteristics' prong may encompass similar, but not necessarily identical, products, while the 'different characteristics' prong may cover significantly different products."

(Response 29) We agree that the district court rejected FDA's interpretation that same characteristics meant that the new and predicate products had identical characteristics. As explained in the proposed rule, we view the same characteristics prong to encompass new tobacco products that are so similar to the predicate product that FDA would not need scientific information beyond identification of the changes to determine whether the new product raises different questions of public health. The examples provided in the preceding paragraphs are intended to further illustrate the changes that might be appropriate to proceed through the same characteristics prong.

(Comment 30) One comment states that FDA should limit any finding that a new tobacco product has the "same characteristics" as a predicate product where the characteristics are not identical and an applicant "demonstrate[s] that the differences, both individually and collectively, cannot plausibly have an effect on individual health or population-level health."

This comment states that at a minimum the applicant should explain all the differences in characteristics and demonstrate that the differences cannot plausibly increase the potential harm to an individual or to the population as a whole. Other comments view as inappropriate FDA's statement that the same characteristics prong would be appropriate for new tobacco products that are "so similar" to the predicate that FDA would not need scientific information to determine whether the new product raises different questions of public health. The comments maintain that a public health analysis should not be part of the same characteristics analysis.

(Response 30) Under the same characteristics prong, an applicant need not demonstrate that any modifications to the new product do not cause the new product to raise different questions of public health. The "different questions of public health" analysis arises under the different characteristics prong. An SE review is structured as a tobacco product to tobacco product comparison, which does not account for population standards. We agree, and the rule requires, that the applicant provide information on the similarities and differences in characteristics between the new and predicate tobacco products (see, e.g., §§ 1107.18(d) and 1107.19). However, we disagree with the comments that suggest that public health considerations generally should not be considered as part of an SE review under either prong. Rather, under the SE pathway, FDA protects the public health by authorizing only new tobacco products that are substantially equivalent to a predicate tobacco product.

(Comment 31) Some comments request additional clarity on the same characteristics prong and suggest that the lack of distinct definitions for "same characteristic" and "different characteristic" creates unclear pathways for manufacturers to follow. For example, one comment finds circular FDA's suggestion that "the 'same characteristics' analysis might be appropriate for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine different questions of public health" while "different characteristics' [is] if a product were dissimilar enough from the predicate product that FDA could not determine without scientific information whether the new product raised different

questions of public health." This comment notes that FDA should determine whether two products have the "same characteristics," and, if so, find the new product substantially equivalent, and, if not, then move to the second prong to determine "whether the new product as a whole raises different questions of public health relative to products in the same category that were on the market as of February 15, 2007."

Similarly, another comment suggests that the "function of the 'same characteristics' prong is to determine whether any difference in characteristics between a new product and its predicate are materially different," stating that materiality is determined by whether such differences raise questions of public health. The comment further argues that if the differences are not material, then the products have the same characteristics. This comment suggests that under the different characteristics prong, a product should be substantially equivalent if requiring authorization under the more demanding PMTA pathway is not appropriate because the product does not raise different questions of public health.

Other comments suggest FDA define "same characteristics" to mean the products being compared have similar, but not identical, materials, ingredients, design, composition, heating source or other features, and the differences are not material to a public health assessment of the new product. The comment proposes FDA might define "different characteristics" to mean the products being compared have material differences in materials, ingredients, design, composition, heating source or other features, such that there is a potential to raise different questions of public health.

(Response 31) The initial decision of whether to submit a change under the same characteristics or different characteristics prong in an SE Report rests with the applicant who is best positioned to understand their new tobacco product, as well as how it compares with the predicate tobacco product. However, it is possible that FDA may determine that an SE Report submitted under the different characteristics prong has the same characteristics, or that FDA may determine that an SE Report submitted under the same characteristics prong has different

characteristics. Note that an applicant's failure to properly identify the type of report will not prevent further review of the SE Report. In addition, although we agree that characteristics that have material differences are likely to fall under the different characteristics prong, we do not agree that a determination as to whether any differences are "materially different" is necessarily a function of the same characteristics prong or that using that term adds much clarity. As noted, we view the same characteristics prong to encompass new tobacco products that are so similar to the predicate product that FDA would not need scientific information beyond identification of the changes to determine whether the new product raises different questions of public health.

The range and scope of comments received on this topic illustrate that codifying definitions that will appropriately address the spectrum of tobacco product and changes that an SE Report might include could be premature and result in inflexibility. Thus, as we discussed earlier in this section, although this final rule continues to include examples of changes that might proceed as same characteristics, we have determined at this time not to proceed with codifying definitions of same characteristics and different characteristics.

(Comment 32) Several comments address whether there are some classes of changes that would not require scientific information to determine whether the new product raises different questions of public health. Some comments note that several examples included in the proposed rule as examples of changes that could proceed as same characteristics in an SE Report should be eligible for the SE Exemption pathway. For example, some comments state that product quantity changes should be exempt from premarket review, although one comment states FDA should not allow a product quantity change to fall under the same characteristics prong of SE. Other comments request that we include additional examples of changes that might proceed as same characteristics in an SE Report, such as changes to low ignition propensity cigarette paper, tipping paper, and tipping paper adhesives, or that we provide a decision-tree.

(Response 32) FDA agrees that certain changes could proceed through either the same characteristics prong or through the SE exemptions pathway, and we disagree with the comment

that suggests that product quantity changes are not appropriate for a "same characteristics" SE Report. At this time, based on the currently available evidence regarding consumer perception and use, changes in product quantity between a new and predicate tobacco product do not cause new tobacco products to raise different questions of public health. As explained earlier in this section of the final rule, we have added examples of changes that are likely to be able to proceed as same characteristics in an SE Report, including a change in tipping paper color from plain to cork where the tipping paper target specifications are identical, a change in adhesive, the removal of a dye or ink, or replacing filter tow with an alternate filter tow with identical target specifications. In addition, as we note above, with more review experience we intend to provide further information and clarification about the Agency's thinking about what kinds of modifications could proceed through the same characteristics prong, different characteristics prong, and/or an exemption request under section 905(j)(3) of the FD&C Act (as implemented at § 1107.1).

(Comment 33) One comment suggests that a change submitted as a same characteristics SE Report could contain all the general information outlined in proposed § 1107.18(c), a certification that all characteristics are identical between the predicate and new tobacco product except for listed changes, a side-by-side design and ingredient comparison, a health information summary statement, and a statement of compliance with any applicable product standards. The comment notes that a same characteristics SE Report should not contain comparative testing data, HPHC testing, or stability testing.

(Response 33) FDA expects that SE Reports submitted under the same characteristics prong will be for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine whether the new product raises different questions of public health. An SE Report submitted under the same characteristics prong must contain the applicable required information set out in § 1107.18 but would not need to include the comparison information as set out in § 1107.19. If an applicant submitting an SE Report

under the same characteristics prong is not able to show that the new tobacco product is eligible for the same characteristics prong, the applicant should proceed under the different characteristics prong which requires the submission of further information, such as comparison of HPHCs data.

(Comment 34) Several comments also state that requiring SE submissions for product quantity changes conflicts with an FDA memorandum that the comments suggest show that FDA has no scientific or other basis to require SE Reports for product quantity changes (this comment references the FDA memorandum, "Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for Statutorily Regulated Tobacco Products." December 2017, available at: https://www.fda.gov/media/124674/download).

(Response 34) We disagree that product quantity changes for tobacco products do not require premarket review. Section 910(a)(1) of the FD&C Act defines a "new tobacco product" as: (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. As explained in *Philip Morris* v. *FDA*, a change in product quantity results in a new tobacco product requiring premarket authorization. *Philip Morris*, 202 F.Supp. 3d at 55-56.

We also disagree that product quantity changes can proceed through the exemption pathway under section 905(j)(3) of the FD&C Act. The FD&C Act establishes when a modification might be exempt from substantial equivalence, stating that FDA may exempt from the requirements of section 905(j) relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910 of the FD&C Act, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the

quantity of an existing tobacco additive (section 905(j)(3) of the FD&C Act; see also § 1107.1). The statute limits the eligible modifications to changes to additives. Therefore, a change in product quantity is not eligible to use the exemption premarket pathway because a change in product quantity, even if combined with a change in additives, is not only a change in additives.

(Comment 35) Another comment requests that FDA extend the product quantity change "streamlined approach" to other modifications and suggests as examples ingredient changes within 5 percent of the target and the replacement of non-Generally Recognized as Safe (GRAS) to GRAS ingredients in smokeless tobacco.

(Response 35) FDA agrees in part with this comment. We agree that other types of modifications can be submitted as a "streamlined" SE Report. FDA has received numerous successful applications where the manufacturer described any modification(s) between the new and predicate tobacco product, and provided a certification statement that all other characteristics are identical. For these SE Reports, FDA expects the applicant to provide adequate data to support that the new tobacco product is substantially equivalent to the predicate (which, for a different characteristics report, would include data to support that the proposed modification between the new and predicate tobacco product does not cause the new tobacco product to raise different questions of public health). A change in ingredient amount within 5 percent of the target specifications of the predicate tobacco product may be found substantially equivalent. This is a case-by-case determination. For example, a change of 5 percent could raise different questions of public health if there is toxicity associated with that ingredient; therefore, scientific data would be needed to ensure that any increase in toxicity does not cause the new tobacco product to raise different questions of public health. Also, if there are ingredient changes within 5 percent of the target specifications for a large number of ingredients (e.g., 30 ingredients), the totality of all modifications may raise different questions of public health.

As with any ingredient change between a new and predicate tobacco product, the applicant must provide adequate information to demonstrate the new tobacco product meets the standard for authorization through the SE pathway.

FDA has received SE Reports that have included a change from non-GRAS to GRAS ingredients. Any ingredient change where the ingredients involved are (1) chemically identical; (2) have the same or nearly the same specifications; and (3) are present in identical or lower quantities, are not expected to raise HPHC quantities. Ingredient changes from non-GRAS to GRAS meet this type of change and therefore are not expected to raise HPHC quantities. In this scenario, FDA agrees no data would be needed beyond that required to identify this change under § 1107.18(g). FDA notes that GRAS designation pertains to foods and is not determinative with respect to the substantial equivalence standard, although in some cases, a GRAS determination and data underlying that determination may be appropriately bridged to tobacco products. As indicated above, changes from one ingredient to a higher grade of that ingredient can qualify as a same characteristics SE Report (e.g., a change from non-USP to USP grade nicotine).

(Comment 36) Several comments generally object to FDA's approach to the "different" characteristics prong stating, for example, that FDA treats every SE Report as a different characteristics SE Report. One comment states that FDA is requiring the same or similar information for both prongs, and that all SE reports in essence would have to submit under the "different" characteristics prong to show the new tobacco product has the same characteristics. The comments state that the approach in the proposed rule is in conflict with Congressional intent.

(Response 36) We disagree with this comment. Both the proposed rule and this final rule illustrate modifications that are likely to be able to fall under the same characteristics prong and thus would not require submission of the information required under § 1107.19, unlike

modifications that fall under the different characteristics prong, which do require submission of the information in § 1107.19.

(Comment 37) Some comments state that the different characteristics prong does not make reference to a predicate tobacco product at all and suggest that the different questions of public health determination should be without reference to a predicate and instead be determined by a comparison to all tobacco products in the marketplace. For example, one comment suggests that FDA "look only to the risks to the public that are of a different type or magnitude from the risks present in the market for the particular category of tobacco product at issue as of the baseline date of February 15, 2007." Similarly, some comments state that because the FD&C Act does not include "predicate product" in the "different characteristics" prong, FDA must evaluate products by comparing the attributes of the product to a broader range of other marketed products (beyond the referenced predicate). These comments generally state that the different questions of public health language included in the second prong is intended to route to the PMTA process those new tobacco products that raise different questions of public health beyond those already recognized, i.e., to identify products that have risks distinct in type or magnitude from the existing, known risks prevalent in the market as of February 15, 2007, and that this should be a "heavy lift" before FDA can conclude that a new product raises different questions of public health.

(Response 37) We disagree with the comment's assertion that the analysis of different characteristics should include consideration of all tobacco products in the marketplace as of February 15, 2007. Both the same characteristics and different characteristics prongs are specific to the comparison between a new tobacco product and its predicate. A marketplace range of products, or multiple predicates, as suggested by the commenter, would be inconsistent with the statutory framework Congress provided for authorization through the SE pathway. Nowhere in section 910(a)(3)(A) or 905(j) of the FD&C Act does the statute state--either explicitly or implicitly--that the SE comparison should be made to the market as a whole as of February 15,

2007. On the contrary, there are numerous references to a single predicate product throughout the sections of the FD&C Act which discuss SE. *See, e.g.,* section 905(j)(1)(A)(i) of the FD&C Act (person seeking to introduce new tobacco product via SE pathway must provide its basis for determination that the new tobacco product is substantially equivalent, within the meaning of section 910, to *a tobacco product commercially marketed* as of February 15, 2007); section 910(a)(2)(A) of the FD&C Act (a PMTA order is required unless FDA has issued an order that the new tobacco product--is substantially equivalent to *a tobacco product commercially marketed* as of February 15, 2007); section 910(a)(3)(A) ("substantial equivalence" means, with respect to the tobacco product being compared to *the predicate tobacco product*); section 910(a)(3)(C) (a new tobacco product may not be found to be substantially equivalent *to a predicate tobacco product* that has been removed from the market or that has been determined by a judicial order to be misbranded or adulterated). There are no references in the FD&C Act that discuss any SE finding in connection with the marketplace or a marketplace range of products. In addition to being inconsistent with the FD&C Act, a comparison to all tobacco products in the "marketplace" would make it difficult and impractical to compare each characteristic between the new and predicate tobacco products. This approach also raises questions as to what should be considered the "marketplace," such as which tobacco products should be used in determining the marketplace and whether the understanding of marketplace shifts over time.

This is in contrast to the evaluation FDA must make to authorize a product through the PMTA pathway. In order to receive authorization through the PMTA pathway, FDA must find that permitting the new tobacco product to be marketed would be "appropriate for the protection of the public health." (See section 910(c)(2) of the FD&C Act.) In making this determination, FDA must evaluate the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or

decreased likelihood that those who do not use tobacco products will start using such products. (See section 910(a)(4) of the FD&C Act.) This is a much different standard and inquiry than that which is undertaken under the different questions of public health analysis under SE.

(Comment 38) One comment states that FDA's intent to judge differences in characteristics individually and in the aggregate under the different characteristics prong "place[s] undue and unreasonable importance on every individual change to a specific ingredient, material, or characteristic, no matter how minor or unrelated to public health, and without any explanation of how FDA will weigh the differences." This comment argues that if true, FDA will be unlikely to determine that any new product is substantially equivalent.

(Response 38) We disagree with the assertion that we will be unable to determine that any new tobacco product is substantially equivalent. FDA has issued a high number of SE orders and a large ratio of such orders relative to not substantially equivalent (NSE) orders. As of December 31, 2019, of the orders issued for regular SE Reports, 80 percent were for an SE finding (a total of 1,009 SE orders versus a total of 209 NSE orders) (information on marketing orders related to substantial equivalence for tobacco products can be found at https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se). Additionally, as of December 31, 2019, FDA had closed 96% of all regular SE Reports accepted. FDA evaluates SE Reports on a case-by-case basis based on the content of the SE Report. Certain changes between the new and predicate tobacco product may affect additional characteristics or impact HPHCs in a way that would cause a new tobacco product to raise different questions of public health. For example, certain changes in design parameters can lead to an increase HPHCs. We also want to note, in response to the concern that FDA's approach places "unreasonable importance on every individual change", "no matter how minor" the change, that for changes that are minor modification to tobacco additives, the exemption from substantial equivalence pathway is available. SE Reports that include changes that FDA believes limited or no information is needed may be eligible to proceed as a "same characteristics" SE

Report, as explained in the examples above, or via a streamlined SE Report containing limited information sufficient to demonstrate the changes subject of that SE Report do not cause the new tobacco product to raise different questions of public health.

(Comment 39) At least one comment states that the considerations included in the proposed rule related to different characteristics and different questions of public health exceed the physical characteristics of the product itself (e.g., that FDA is requiring that applicants examine the potential to increase initiation, increase abuse liability, or decrease cessation). The comment further argues that, if FDA is requiring applicants to address whether every change has the potential to affect any of these outcomes, it is requiring manufacturers to meet a subjective, unmeasurable standard contrary to law, i.e., FDA appears to want manufacturers to prove a negative.

(Response 39) We disagree that these considerations do not relate to the physical characteristics of a tobacco product. Rather, a modification to a tobacco product may cause the new tobacco product to have different characteristics from the predicate tobacco product. When a new product has different characteristics, FDA evaluates whether the totality of difference(s) in characteristics do not cause the new product to raise different question of public health. Congress stated that the Tobacco Control Act's "purposes" include ensuring that the FDA has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco and promoting cessation to reduce disease risk and the social-costs associated with tobacco-related diseases (Tobacco Control Act sections 3(2) and (9)). In addition, as explained above, Congress defined substantial equivalence to mean that the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health. (See section 910(a)(3)(A)(ii) of the FD&C Act.) The reference to "this section" is a reference to the PMTA pathway. Because one of the bases for FDA finding that a product is appropriate for the

protection of public health (i.e., the PMTA "standard") includes the increased or decreased likelihood that existing users will stop using and new users will initiate use of such products, it is reasonable to examine those same considerations under the SE standard to determine whether the differences between the predicate and the new product show that the product should be reviewed under the PMTA pathway. Thus, as part of making the "different questions of public health" determination, FDA typically considers whether the new product has potentially higher HPHC yields, toxicity, initiation, abuse liability, or dependence relative to the predicate product.

(Comment 40) Some comments disagree with the proposed rule's discussion of the phrase "different questions of public health" (DQPH) and state that FDA's thinking is incorrect. Other comments note that the six identified factors included in the proposed rule for determining if a new tobacco product raises different questions of public health seem optional, non-exhaustive, and vague.

(Response 40) We agree that additional information may assist applicants in understanding DQPH. Thus, in the following paragraphs FDA is providing further information on our thinking related to this phrase. Specifically, in evaluating whether an applicant has demonstrated that a difference in characteristic does not cause the new product to raise different questions of public health, FDA may consider, among other public health considerations, whether:

- The new tobacco product has higher HPHC yields compared to the predicate tobacco product, and the difference in HPHC yields is greater than the analytical variability of the method used to detect it.[8]
- The new tobacco product has potentially higher toxicity due to an appreciable increase in an ingredient associated with adverse health effects, compared to the predicate tobacco product. For example, the evaluation of the available toxicology

[8] In determining whether an applicant has demonstrated that any differences in characteristics do not cause the new product to raise different questions of public health, FDA will consider whether increases in certain HPHCs are offset by decreases of other HPHCs.

information may show that an increase in an ingredient between the new and predicate tobacco products demonstrates an increase in cancer risk or non-cancer hazard for users of the new tobacco product compared to those of the predicate tobacco product, and thus causes the new tobacco product to raise different questions of public health.

- The new tobacco product compared to the predicate has the potential to affect use behavior such as an increase in initiation of the product, especially among youth or other vulnerable populations; a decrease in cessation; or use by different tobacco-use status groups.
- The new tobacco product compared to the predicate has potentially higher abuse liability.
- The new tobacco product has the potential to increase dependence.

Based on these considerations, as well as other public health considerations, FDA will determine whether the applicant has demonstrated that any differences do not cause the new tobacco product to raise different questions of public health.

(Comment 41) Other comments request that FDA include a definition of the phrase "different questions of public health" in the final regulation. The comments assert that industry needs this information to determine the appropriate pathway for its SE submission. Some comments propose definitions of the phrase; for example, one comment proposes to define the phase "different questions of public health" to mean when "the new product as a whole raises questions of public health that are significantly different in type and magnitude from those presented by [Pre-Existing tobacco products] or other legally marketed tobacco products." The comments contend that the analysis should look at "different questions of public health" as a whole rather than the implications of the particular product as compared to another product. One comment suggests that an applicant could satisfy the public health analysis by providing HPHC data for both the new and predicate products, and if none of the HPHCs for the new product are

statistically higher than the predicate product, then the new product should pass the public health analysis. The comment suggests that applicants could submit a quantitative risk assessment (QRA) (defined by the comment as a magnitude of individual disease risk tool), and if the new product is of no greater risk than the predicate product then the new product should pass the public health analysis. This comment also suggests that FDA should establish a QRA framework and "identify the number of product runs or batches necessary to generate HPHC data," as well as publish this data so that manufacturers can generate QRA category curves.

(Response 41) We agree that changes in characteristics could cause the new tobacco product to raise "different questions of public health" where "the new product as a whole raises questions of public health that are significantly different in type and magnitude from those presented by [Pre-Existing] or other legally marketed tobacco products." However, instead of adopting a definition, we include additional details in the preceding paragraphs on what we may consider when determining if a new tobacco product raises different questions of public health. The public health analysis of an SE Report involves the evaluation of all toxicologically relevant changes, including HPHCs, but also non-tobacco ingredient changes that may cause the new tobacco product to raise different questions of public health. At this time, we are not recommending the inclusion of QRA with SE Reports, as they are often not needed for the comparison of HPHCs from the new and corresponding predicate tobacco products. In situations where an applicant believes that a QRA would be informative in evaluating the comparison between a new and predicate tobacco product, we strongly encourage the applicant to contact FDA on the methodology and applicability of a potential QRA before an applicant voluntarily develops or submits a risk assessment.

(Comment 42) Another comment asserts that a definition of different questions of public health should include information that indicates a product with a low usage rate will not impact public health.

(Response 42) We disagree with the assertion that new tobacco products with low usage rates would necessarily not impact public health. Under section 905(j)(1)(A)(i) of the FD&C Act, the basis for determining substantial equivalence is through the comparison of the new tobacco product to the predicate tobacco product. Therefore, providing prevalence of use (even if it indicates low usage) of the new tobacco product without comparison to prevalence of use to a predicate tobacco product is insufficient to determine if the new tobacco product raises different questions of public health. In addition, differences in the composition of users of the new and predicate tobacco products may still raise DQPH even with low overall prevalence of use. Furthermore, FDA's assessment of the product's impact on public health goes beyond usage rate. For example, a new tobacco product that has a low usage rate, but is found to be more toxic than the predicate tobacco product (e.g., a tobacco product with higher HPHCs than the predicate tobacco product) could raise different questions of public health and be found not substantially equivalent. Moreover, prevalence can change over time, and it can be difficult to predict the prevalence of a new product before it is marketed.

- *Tobacco product*

We proposed to include the statutory definition of tobacco product (section 201(rr) of the FD&C Act (21 U.S.C. 321(rr))). In the FD&C Act, tobacco product is defined as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the FD&C Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g) (21 U.S.C. 353(g))). We discuss the comment related to this definition in the following paragraphs, and we are including this definition in the final rule without change.

(Comment 43) At least one comment disagrees with FDA's interpretation of tobacco product (i.e., as encompassing the whole product and not limited to a single unit or portion) and argues that FDA's interpretation is too broad, misinterprets the FD&C Act, and is unnecessary.

(Response 43) We disagree with these objections related to the language included in the proposed rule's discussion of new tobacco product and tobacco product. Rather, as noted in the proposed rule, and supported by the *Philip Morris* decision, for purposes of determining whether a tobacco product is new under section 910 of the FD&C Act, and therefore requires premarket authorization prior to marketing, a "tobacco product" encompasses the whole product (e.g., a pack of cigarettes or a tin of loose tobacco), and is not limited to a single unit or portion of the whole product (e.g., a single cigarette or a single snus pouch). (*See Philip Morris*, 202 F. Supp. 3d at 55-57.) If an SE Report includes information on only a portion of a new tobacco product, FDA would have an incomplete understanding of the tobacco product (e.g., FDA may not get information on the container closure system, which could impact the consumable product) and would not be able to determine, for example, potential impacts on initiation and cessation of tobacco use (information which may be needed for determining whether there are DQPH).

- *Tobacco product manufacturer*

We proposed to include the statutory definition of tobacco product manufacturer in the rule (section 900(20) of the FD&C Act). The statute defines tobacco product manufacturer as any person, including a repacker or relabeler, who: (1) manufactures, fabricates, assembles, processes, or labels a tobacco product or (2) imports a finished tobacco product for sale or distribution in the United States. In the following paragraphs, we discuss the comments related to this definition. We are including this definition without change in the final rule.

(Comment 44) One comment requests that FDA clarify that "an entity that contracts with another domestic entity to manufacture a tobacco product" is included in this definition.

(Response 44) The rule includes the definition of tobacco product manufacturer from the FD&C Act, stating that "tobacco product manufacturer" includes any repacker or relabeler and

any person who manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States (this term and definition are included in the final rule). Under this definition, contract entities engaged in the activities described in the definition of a tobacco product manufacturer would fall within the scope of the definition of tobacco product manufacturer.

D. Comments on Subpart C--Substantial Equivalence Reports and FDA Responses

1. Submission of an SE Report (§ 1107.16)

Proposed § 1107.16 would establish when an applicant should submit an SE Report. We received no comments on this proposed section, and we are finalizing this section without change.

2. Content and Format of an SE Report (§ 1107.18)

Proposed § 1107.18 set out the required content and format of SE Reports. This proposed section included requirements related to: (a) overview; (b) format; (c) general information; (d) summary; (e) new tobacco product description; (f) description of predicate tobacco product; (g) comparison information; (h) comparative testing information; (i) statement of compliance with applicable tobacco product standards; (j) health information summary or statement regarding availability of such information; (k) compliance with part 25 (21 CFR part 25); and (*l*) certification statement. Proposed § 1107.18(b) and (c) also included requirements for the use of Form FDA 3964 (Tobacco Amendment and General Correspondence Report) and Form FDA 3965 (Tobacco Substantial Equivalence Report Submission) (Refs. 8 and 9).

After considering the comments, we are revising § 1107.18 in several places for consistency with other changes to the rule and to add clarity. Specifically, in § 1107.18(a), we have revised language that previously referred to "grandfathered" to reflect the statutory language related to what types of tobacco product can serve as predicate tobacco products. We also added in paragraph (a) a cross-reference to § 1105.10 to clarify that FDA generally intends to refuse to accept an SE Report for review if it does not comply with both §§ 1105.10 and

1107.18 to help ensure applicants are aware that the requirements of both sections must be satisfied. As we explain further below, we have made modifications to § 1107.18(g) and (h) to clarify what information is needed for acceptance for further review.

We are also revising § 1107.18(c)(4) to add "voluntary" as a modifier to "request" to further emphasize that seeking an FDA determination relating to a potential predicate tobacco product is a voluntary process. We revised § 1107.18(c)(5) and (6) to add "including email address" as information the SE Report must include to help ensure we have complete contact information.

We revised § 1107.18(c)(7)(iii) (product category, product subcategory, and product properties table) to help ensure that we are able to identify and evaluate each product more accurately and efficiently for purposes of SE review. Under this revised taxonomy, some tobacco products may fit under more than one category. For example, the cigarette product category no longer lists noncombusted cigarettes as a subcategory. Instead, for purposes of SE review, a "heated tobacco product" category has been added to the identification tables. This SE review category should be used for (among others) tobacco products that meet the definition of a cigarette but are not combusted (products that do not exceed 350°C). Heated tobacco products (HTP) can be used with e-liquids, other types of tobacco filler, or consumable (e.g., wax, oils). If, however, a tobacco product can be used only with e-liquids, it should be captured under ENDS and not the HTP category. To ensure we have all the information we need to efficiently and effectively review your application, if the product that is the subject of your application is a heated tobacco product and is not an ENDS product, you should submit information under §§ 1107.18(c)(7)(iii) and 1107.19(a)(21) under the heated tobacco product category.[9] FDA believes these product categorizations will help ensure that applications include the most relevant

[9] The categorization of HTPs as a separate category from cigarettes in this rule, as demonstrated in §§ 1107.18(c)(7)(iii) and 1107.19(a)(21), does not extend to other legal requirements beyond those associated with the SE review process.

information for their product, which in turn will speed up FDA's review and ability to reach an authorization decision.

Other changes to § 1107.18(c)(7)(iii) include FDA's clarification under the "cigar" category to designate "leaf-wrapped" cigars as *unfiltered* to more accurately describe the product category, as "leaf-wrapped" cigars typically do not include filters; and under the "waterpipe" category, waterpipe "diameter" has been added to distinguish between waterpipes of different sizes (width/diameter and height) where all other uniquely identifying information is the same; under the "pipe tobacco filler" category, "tobacco cut style" has been added to distinguish between different cut pipe tobacco filler e.g., standard cut, such as shag cut, bugler cut, loose cut, etc., or a pressed cut, such as flake, cube cut, roll cake, etc. or a mixture. Additionally, FDA has removed the requirement to provide tobacco cut size from the unique identification requirements for smokeless tobacco and cigar tobacco filler. A specific numerical value for this field is not necessary to uniquely identify the specific product to which the SE Report pertains, as it can be described further through identification of additional properties (e.g., fine cut, long cut). However, for the purposes of determining whether characteristics related to tobacco cut size cause the new tobacco product to raise different questions of public health, information to determine tobacco cut size is required under § 1107.19 for the product categories specified in that section.

Across all product categories, the subcategory of "co-package" has been removed from § 1107.18(c)(7)(iii). If an applicant submits an SE Report for a co-packaged tobacco product, the unique identification of this co-packaged product would include the specific items needed to identify each product within the co-package. For example, if the co-package is a pouch of roll-your-own (RYO) tobacco filler that contains rolling papers inside the pouch, the applicant would identify the tobacco product as a co-packaged product and provide the unique identification for both RYO tobacco filler and rolling papers.

In § 1107.18(d)(2), we have added "any differences in characteristics do not cause the new tobacco product to" instead of "does not" to clarify that this part of the sentence refers to differences in characteristics.

In § 1107.18(e), we are deleting "including the fermentation process, where applicable, with information on the type and quantity of the microbial inoculum and/or fermentation solutions" as the SE Report does not need to include this as part of a concise overview of the process used to manufacture the new tobacco product. The information that would have been submitted under this proposed requirement would also be duplicative of the fermentation information that will be submitted as part of the SE Report under § 1107.19.

In § 1107.18(f), for the reasons explained earlier in this preamble, we have removed references to "grandfathered" and instead use language that reflects the statutory definition of predicate tobacco product. We are also deleting from § 1107.18 proposed paragraph (f)(2)(i), which would have required the predicate tobacco product to be in the same product category and subcategory as the new tobacco product and making corresponding renumbering edits to this subsection. As we discuss in later paragraphs, we are removing this requirement because although it will likely be difficult for an applicant to demonstrate substantial equivalence in this situation (where the new product is in a different category or subcategory as its selected predicate), it may, in rare cases, be possible for an applicant to make a showing of substantial equivalence. In § 1107.18(f)(2)(iii) (formerly (f)(2)(iv)), we have changed "rescission order" to "rescission action," which is a more accurate description.

In § 1107.18(g), we have made some minor clarifying edits, and in § 1107.18(h) we have added "that has been demonstrated to be fully validated" following comparative testing, which is needed to ensure the method is fit for purpose and the measured values can be accurately compared between a new and predicate tobacco product. FDA considers full validation of a quantitative analytical procedure to include: (1) accuracy; precision (repeatability, intermediate precision, and robustness); (2) selectivity; (3) sensitivity (limit of detection and limit of

quantification); (4) linearity; and (5) range. The performance criteria typically include information such as the target analyte, an approximation of the range of concentrations of the analyte in the sample, the intended purpose of the procedure (e.g., qualitative, quantitative, major component, minor component, etc.), and the number of samples to be analyzed.

We have also corrected minor typographical errors in proposed § 1107.18(g) and (k)(2). We have also removed the phrase "as described in § 1107.19" from § 1107.18(g) and (h) to better reflect that FDA's determination of acceptability for review is not intended to be an exhaustive review of the SE Report but rather is intended to serve as a check that the SE Report generally includes required information before FDA accepts an SE Report and proceeds to substantive review. For the same reason, we also moved the detailed requirements related to comparative testing from proposed § 1107.18(h) to § 1107.19.

Both "same characteristics" and "different characteristics" SE Reports must provide the information required by § 1107.18(g). As explained in § 1107.18(g), if the new tobacco product has limited changes to a characteristic(s) when compared to the predicate tobacco product, and all other characteristics are identical (e.g., a change to product quantity), the applicant must provide comparison information related to any characteristic(s) that have changed, but may certify that the other characteristics are identical under §1107.18(*l*)(2).

Where the new tobacco product has the same characteristics as the predicate tobacco products, applicants need only explain that their SE Report is a "same characteristics" report to satisfy the requirement of § 1107.18(h). Furthermore, as explained in § 1107.18(h), an applicant need not provide comparative testing information for any characteristics that are identical between the new tobacco product and the predicate tobacco product, and for which the applicant has certified that the characteristics are identical under §1107.18(*l*)(2).

The following paragraphs describe the comments we received on proposed § 1107.18 and our responses to those comments.

- *Forms (§ 1107.18(b)-(c))*

Proposed § 1107.18(b) and (c) included requirements that the applicant use the forms that FDA provides when submitting an SE Report. Following our consideration of the comments related to the forms, we are finalizing these requirements without change. We describe the comments to these subsections and our responses next.

(Comment 45) At least one comment states that use of the FDA forms should be optional rather than mandatory.

(Response 45) We disagree. As explained in the proposed rule, the requirements in this rule, including use of these forms, are intended to provide clarity to applicants with respect to what they must submit in an SE Report and to help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007. Additionally, use of a standardized form allows FDA to receive information in a way that allows for faster processing and uploading of the SE Report and its contents, thereby increasing efficiency of the review process.

(Comment 46) One comment believes FDA has underestimated the time needed to complete the forms and did not explain how it arrived at these estimates.

(Response 46) FDA conducted a thorough analysis of the current paperwork burden associated with the SE program and other similar forms. After a further review of similar forms, we have adjusted Form 3965 to 45 minutes per response and Form 3964 to 10 minutes per response. Using our knowledge of elements in an SE report FDA believe we have applied the most accurate burden to the forms. Beyond entering data into the form, we conclude that the burden for searching existing data sources and gathering and maintaining the data needed, is accounted for in the burden charts. FDA notes that the commenter did not provide a recommendation for alternative estimates (see also section IX of this final rule).

(Comment 47) Another comment notes that although FDA appears to recognize that the evidence required in an SE Report depends on whether the new tobacco product has the “same”

characteristics as the predicate product or if the new tobacco product has "different" characteristics than the predicate product, this distinction is not reflected in either the draft of Form FDA 3965 or the rule itself.

(Response 47) The form has been revised to include a section where the applicant would distinguish whether they are submitting a "same characteristics" SE Report, or a "different characteristics" SE Report. A "same characteristics" SE Report must describe the modification(s) and include all of the other information required in § 1107.18. As described in previous paragraphs, however, an SE Report submitted under the same characteristics prong would not be required to provide the information described in § 1107.19.

- *General information (§ 1107.18(c))*

Proposed § 1107.18(c) listed the information that the SE Report would be required to include. This information included general administrative information specifying the type of submission (e.g., SE Report or amendment to a report); unique identification of both the new and the predicate tobacco products, as well as contact information. Following our consideration of comments, we are finalizing § 1107.18(c) with changes to reflect updates to § 1107.18(c)(7)(iii) (related to product category, product subcategory, and product properties).

(Comment 48) Several comments request clarity regarding the proposed requirement that an SE Report include information about the product's characterizing flavor. Specifically, the comments request FDA to clarify the requirement or include a definition of the term, or seek to understand if the purpose of the requirement is simply to see how the applicant identifies the product (e.g., "no characterizing flavor" or a "particular flavor"). Some comments note that the only information available is in an FDA memorandum, and they disagree with how the memorandum explains that characterizing flavor should be indicated by factors including chemical composition or olfactory response (the comment cites an FDA document, entitled, "Unique Identification of Tobacco Products," November 2016, which is available at: https://www.fda.gov/media/124658/download). Other comments request that FDA consider only

the toxicological effects rather than the effect on user behavior, when considering the differences in characterizing flavor between the new and predicate tobacco products.

(Response 48) This final rule does not define characterizing flavor. As part of uniquely identifying a new and predicate tobacco product, the SE Report must include product property information on whether the products have a characterizing flavor or not. The SE Report may state, for example, that a new cigarette has "none" for the product property of characterizing flavor. In addition, this information is needed as part of fully characterizing a new tobacco product to aid FDA during the review process and in making an SE determination. When considering the differences in characterizing flavor between the new and predicate tobacco products, FDA considers both the toxicological effects and the effects on user behavior.

(Comment 49) At least one comment indicates general disagreement that a change in characterizing flavor should require submission of an SE Report. The comment states that, if a new product includes a different flavoring from the predicate, FDA should not require that an SE Report be submitted for that new or different flavor but that, if an SE Report is required, the product should not "fail" SE review "unless the addition of flavor alters the chemistry of the product such that it increases the inherent risks of tobacco-related diseases in an individual user either through the introduction of new or greater HPHCs." A comment also states FDA has not explained why a change in characterizing flavor would require submission of an SE Report for a product with different characteristics.

(Response 49) We disagree that an SE Report should not be required for a change in characterizing flavor. Section 910(a)(1) of the FD&C Act establishes that any modification results in a new tobacco product. A change to or addition or deletion of ingredients that make up a characterizing flavor renders a tobacco product "new." For FDA to make an SE finding, the SE Report must demonstrate that the new tobacco product is substantially equivalent to the predicate tobacco product. As we explain in previous paragraphs related to the definition of substantial equivalence, at this time, an SE Report for the removal of a characterizing flavor is likely to be

able to come in as a same characteristic SE Report as FDA has found such a change does not require scientific data to show that the change does not cause the new tobacco product to raise different questions of public health.

- *New tobacco product description (§ 1107.18(e))*

(Comment 50) Several comments object to requiring any manufacturing information, such as the "concise overview of the process used to manufacture the tobacco product" as provided in this subsection as unnecessary in an SE review. These comments note that FDA should address manufacturing procedures through manufacturing practice regulations issued under section 906(e) of the FD&C Act (21 U.S.C. 387f). Another comment disagrees with these comments, stating that information on manufacturing practices is important to ensure that products are consistently produced.

(Response 50) We agree with the comment suggesting that information on manufacturing practices can be relevant to an SE determination. Note, however, that a concise overview of the process used to manufacture the new tobacco product is only needed where the manufacturing process for the new tobacco product could affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report. If the manufacturing process for the new tobacco product does not affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report, an applicant must state that to satisfy § 1107.18(e)(3).

As explained in the proposed rule, this overview would not need to be an exhaustive discussion but enough information to enable FDA to fully understand and compare the characteristics that can be affected by the manufacturing process of the new tobacco product and the predicate tobacco product. FDA has found during reviews of SE Reports that changes in manufacturing may impact the characteristics of the tobacco product, e.g., the quantities of nicotine (total and free), as well as HPHCs such as TSNAs. Such changes could cause the new product to raise different questions of public health, e.g., an increase in TSNAs may increase the risk for certain types of cancer (Ref. 10).

We disagree with the comments that suggest this information would be more appropriately required through manufacturing practices regulations issued under section 906 of the FD&C Act. Section 906 authorizes FDA to issue regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice. Such regulations could include comprehensive requirements on purchasing controls, production and process controls, and requirements related to acceptance activities and nonconforming products (see, e.g., 21 CFR part 820). In comparison, § 1107.18(e)(3) requires only a "concise overview" of the process used to manufacture the new tobacco product" to aid FDA in understanding in how the manufacturing process might affect the characteristics (or, if the manufacturing process does not affect the characteristics of the new tobacco product beyond what is described elsewhere in an SE Report, an applicant may simply state that). The requirement for a concise overview is vastly different from the manufacturing information that may be required under a tobacco products manufacturing practices regulation under section 906 of the FD&C Act. Moreover, the purpose of the requirement in § 1107.18(e)(3) is not for the purposes described in section 906 of the FD&C Act but, rather, is to help ensure enough information to enable FDA to fully understand and compare the characteristics that can be affected by the manufacturing process of the new tobacco product and the predicate tobacco product.

- *Description of the predicate product (§ 1107.18(f))*

As described in an earlier paragraph in this section, we have made changes to this subsection for consistency with changes that we made to the definition of predicate tobacco product and other clarifying edits. We also removed the requirement that a tobacco product to which a new tobacco product is compared be in the same category and subcategory of product as the new tobacco product. In the following paragraphs, we describe the comments we received on this subsection and our responses.

(Comment 51) Some comments object to the proposed requirement that the new and predicate products be in the same category and subcategory. The comments state, "there is nothing in the statute to prohibit the attempted use of cross-category comparisons in an SE submission" and also refer to the deeming final rule as suggesting such a comparison is appropriate. The comments state that while cross-category comparisons may be more burdensome or require more information, the comparison may be appropriate and, therefore, applicants should be permitted to attempt it.

(Response 51) After careful review of the comments submitted and our own experience, we agree and are no longer requiring that the new and predicate products be in the same category and subcategory. We note that it would likely be difficult for an applicant to demonstrate substantial equivalence where the new product is in a different category or subcategory as its selected predicate, but it may, in rare cases, be possible for an applicant to make a showing of substantial equivalence. For example, an applicant may be able to compare a new snus tobacco product to a pouched moist snuff predicate tobacco product.

It continues to be critical, however, that an applicant select an appropriate predicate tobacco product and provide the scientific evidence demonstrating the new tobacco product is substantially equivalent to that predicate. Even where there are differences in the category or subcategory between the new and predicate tobacco products, FDA could issue an SE order if the applicant provides scientific evidence that demonstrates to FDA that differences between the new product and the predicate product do not cause the new tobacco product to raise different questions of public health. Comparison of a new and predicate tobacco product is much easier, and more likely to result in a finding of SE, if the new and predicate tobacco products are of the same category and subcategory, as the basic characteristics of the predicate and new products are likely to be more similar. For example, manufacturers of ENDS may find it difficult to show that their product is substantially equivalent to a combusted cigarette or a smokeless tobacco product because of the differences in product properties.

If an applicant chooses to compare a new and predicate tobacco product that are not in the same category or subcategory, for FDA to be able to conduct a review of the SE Report, the applicant should provide a strong scientific justification for why a product that may differ from the new tobacco product in even the most basic of characteristics and parameters is an appropriate predicate and how any differences in characteristics do not cause the new tobacco product to raise different questions of public health. For example, where the new and predicate tobacco products are not in the same category or subcategory, an applicant could provide information to demonstrate that users or likely users of the new product display very similar tobacco product use behaviors (e.g., likelihood of initiation, experimentation, switching, dual-use/polyuse, or cessation, as well as actual use patterns, frequency and amount of use) in addition to information on comparison of HPHCs exposure.

(Comment 52) One comment agrees with the proposed requirement of § 1107.18(f) that an applicant include a single predicate product for comparison and that a composite predicate tobacco product would be inconsistent with the FD&C Act. Other comments disagree with FDA's proposal to require manufacturers to identify a single predicate product to compare to the new product. Several of these comments contend that manufacturers should be able to use multiple predicates in a single SE report, stating that permitting the use of multiple predicates would be more consistent with statutory design and also align with the substantial equivalence requirements for devices in sections 510(k) and 513(g) of the FD&C Act. The comments state that we have been inconsistent in our position regarding the use of predicate products and contend that the one predicate approach described in the proposed regulation would create problems for manufacturers because it does not allow for product innovation. In support of this, some comments refer to FDA webinars that suggest that use of two predicates would be appropriate, an FDA decision to permit two predicates to be used for a smokeless product, and an FDA policy memorandum that acknowledges "multiple predicate tobacco products are identified in an SE Report" (this comment referenced the FDA memorandum FDA, "Use of Surrogate

Tobacco Products in SE Reports," September 2016. Available at: https://www.fda.gov/media/124665/download). Some comments ask that, if the final rule maintains the single predicate approach, applicants be permitted to amend currently pending SE Reports to designate the most appropriate predicate product.

(Response 52) We disagree that the final rule should permit the use of multiple predicate tobacco products in an SE Report. There is nothing in the statutory language to support the assertion that the SE comparison can be made to a range of predicate products, and doing so would be inconsistent with the premise of SE review. Creating a new tobacco product from a range of predicate tobacco products can raise different questions of public health beyond those questions raised by the individual predicates because of the way the various additives and other features of a tobacco product interact to impact how chemicals are handled by the body. Some of the ways chemicals can interact is to alter how they are absorbed into the body, metabolized by the body, or how they bind to receptors in the body.

For example, acetaldehyde when present at a level that is below its independent reinforcing effect could boost the reinforcing effect of nicotine, the primary addictive substance in tobacco, beyond what it would be without acetaldehyde present or the sum of the two independent effects (Refs. 11 and 12). If a component from one predicate that contains nicotine is mixed with a component from another predicate that contains acetaldehyde, the synergistic effect of this mixture could raise different questions of public health beyond the separate predicates, because the addictiveness of the product could be greater than either independently or the sum of the two predicate products alone and may reduce cessation and increase initiation, thereby impacting public health.

Finally, the comments also cite instances where it appears that FDA has suggested or permitted reference to two predicate tobacco products. However, in the past, if an SE Report referenced multiple predicate tobacco products, we generally have either broken this down into multiple reports or have used a single predicate tobacco product for comparison. This approach

can result in delays in processing or reviewing an SE Report, which the final rule seeks to prevent by requiring use of single predicate tobacco product. With respect to the comment that requests that FDA permit this for pending SE Reports, as explained in previous paragraphs, this rule does not apply to pending submissions.

(Comment 53) Some comments suggest that requiring that predicate tobacco products be "fully characterized" would be too restrictive and have an anticompetitive impact. These comments state that the level of detail required to fully characterize a predicate tobacco product would necessarily limit each manufacturer to using its own products as predicates and would become too difficult with the passage of time. The comments also suggest there is no public health purpose to requiring these data on predicates.

(Response 53) We disagree. Demonstrating substantial equivalence necessitates a comparison of physical characteristics between a new and predicate tobacco product. In the absence of predicate product characteristics, FDA is unable to conduct scientific review and fulfill its statutory obligation. If an applicant does not have access to a predicate product or wishes to use a predicate product they do not own, one option is the use of a Tobacco Product Master File (TPMF) (see, e.g., the guidance entitled "Tobacco Product Master Files, which can be accessed at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files). A TPMF is a file that is voluntarily submitted to the Center for Tobacco Products (CTP) that contains trade secret and/or confidential commercial information about a tobacco product or component that the owner does not want to share with other persons. TPMFs are a beneficial tool for manufacturers, component suppliers, and ingredient suppliers, and can assist the tobacco product submission process. Also, as discussed in the following paragraph, if an applicant no longer manufacturers a predicate product, it can be remanufactured and tested for the purposes of SE review, or a surrogate may be appropriate for use in place of the actual predicate tobacco product.

- *Comparison information (§ 1107.18(g)) (Surrogates)*

In the proposed rule, in the description of § 1107.18(g), FDA requested comment on the use of information from surrogate tobacco products where there is inadequate data available for the new or predicate tobacco product. FDA received several comments on the use of information from surrogate tobacco products.

(Comment 54) One comment states that manufacturers should not be able to use a surrogate tobacco product in the place of a predicate tobacco product. The comment argues that there is no statutory basis for allowing this, and requests FDA to remove this from the final regulation.

(Response 54) Under the statute, applicants must submit an SE Report that provides information to support that a new tobacco product is substantially equivalent to a predicate tobacco product. The use of surrogate tobacco products in certain situations does not change those statutory requirements. Although permitting use of a surrogate tobacco product may provide an opportunity for applicants to provide stand-in information in lieu of the precise predicate product itself, it is the applicant's responsibility to provide FDA with adequate bridging information for FDA to determine that it is appropriate to extrapolate the data provided on the surrogate tobacco product to the actual predicate product. Ultimately, FDA makes a determination as to whether or not the new product is substantially equivalent to the selected, valid predicate product.

(Comment 55) Several comments request that FDA provide more information regarding the use of surrogate tobacco products, including whether these may be used for SE Reports for cigars. Some comments request that FDA define a surrogate product in the final regulation or that FDA clarify when and how surrogate data may be used, to ensure that its use is applied consistently across applicants and FDA reviewers. The comments on this topic request more clarity on the use of surrogates to assist applicants in providing sufficient information about the surrogate in their submissions.

(Response 55) Although we are not adding a definition of "surrogate tobacco product" to this final rule, for the purposes of an SE review, FDA considers a surrogate tobacco product to be a tobacco product, other than the predicate or new tobacco product that is the subject of the SE Report, for which data are available (or can be generated) and may be scientifically bridged or extrapolated to the predicate or new tobacco product. A surrogate tobacco product is not a fictional tobacco product, but an actual product for which there are empirical data.[10] FDA believes that, when appropriate, applicants, regardless of category of tobacco product, may use a surrogate tobacco product but should clearly designate the specific parts of the SE Report for which the surrogate tobacco product is to be used.[11] Such a surrogate tobacco product may be used, where appropriate, by an applicant looking to demonstrate the substantial equivalence of a new cigar product as compared to a valid predicate.

FDA believes it would only be appropriate to use a surrogate tobacco product when the relevant data are not available for the new or predicate tobacco product and the surrogate tobacco product data can be scientifically bridged to the new or predicate product. Data for a surrogate tobacco product may be provided in place of data for the new or predicate tobacco products, but applicants should provide a scientific justification for why it is reasonable to use the surrogate data and then bridge between the surrogate data and the new or predicate tobacco product. For example, if stability data for a smokeless predicate product are not available, but there is a smokeless surrogate product for which there is stability testing data that can be bridged to the

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[10] Note that a predicate tobacco product that is no longer being manufactured may be reproduced using the design parameters, tobacco blend, structural materials, and ingredients that are identical to those of the predicate tobacco previously produced, and, in this case, FDA would consider the reproduced predicate product to be the predicate product. But if the reproduced predicate product differs from the predicate product in any characteristic, FDA would consider the product to be a surrogate and the applicant would have to supply appropriate bridging information to the selected predicate product. For example, if the reproduced predicate product has the same tobacco blend (percentage of tobacco type) and tobacco curing process as the predicate product, FDA would consider the reproduced predicate product to be the predicate product, even if the crop years are different. If, however, there is any change in the amount of ingredients, including grade and purity or in materials or design parameters, including any change to a manufacturing process that would affect design parameters, FDA would consider the reproduced product to be a surrogate tobacco product.

[11] Surrogate products are not predicate tobacco products. Evidence of commercial marketing for surrogate products is not appropriate to determine whether the predicate tobacco product is a tobacco product commercially marketed (other than for test marketing) as of February 15, 2007.

predicate (e.g., through data on the water content and activity, tobacco (blend and format), ingredients, and container closure), these data could be used for the missing predicate stability data. Similarly, if smoking regimen data (intense and non-intense) for the predicate tobacco product are not available, test data from a surrogate tobacco product could be appropriate if the predicate and surrogate tobacco products can be bridged through data (e.g., ventilation, paper, tobacco blend, filtration). However, surrogate products should not be used for the purpose of extrapolating *target* specifications and *range limits* from a surrogate product to a new product (emphasis added). This is because target specifications and range limits should be specified by the manufacturer for the new tobacco product. If an applicant chooses to use a surrogate tobacco product, we recommend an SE Report include the following information related to the surrogate product:

- The tobacco product to which data on the surrogate product is to be bridged (e.g., predicate product);
- A detailed description of the ingredients in the surrogate product, noting any difference(s) in ingredients from the bridged tobacco product (i.e., the new tobacco product or predicate tobacco product);
- Design parameters of the surrogate product (e.g., cigarette paper base paper porosity, ventilation, tobacco cut or particle size);[12]
- An identification in a side-by-side list of the specifications for ingredients and additives, and materials and design parameters, that differ between the surrogate and the tobacco product to which data (e.g., HPHC or stability) on the surrogate product is to be bridged, including tobacco blend or other ingredients, design parameters, and

[12] For example, if an applicant submits HPHC data from a surrogate combusted filtered cigarette in lieu of HPHC data from a predicate combusted filtered cigarette, the applicant could explain that the surrogate data are appropriate for FDA to consider because the surrogate and predicate tobacco products are identical with the exception of tobacco blend differences. The SE Report also should include data that show those differences are not expected to cause the surrogate tobacco product to yield significant differences in HPHC when compared to the predicate product. Please note that this is just one approach, and FDA expects that the scientific justification for use of the surrogate tobacco product may vary from case to case and depend on the type of differences (e.g., in tobacco blend, design features) between the surrogate tobacco product and the new or predicate tobacco product.

materials such as pouch, filter tow, or paper. To facilitate review and reduce FDA requests for clarification, FDA recommends that side-by-side comparisons of the surrogate and corresponding predicate or new product be provided in tabular format. Where any difference in the characteristics of the products has the potential to impact the use of test data between the surrogate and predicate or new tobacco product, a scientific justification that explains how the surrogate data may be bridged to the predicate or new product will help FDA evaluate whether the surrogate is appropriate. We recommend that the SE Report include supporting information, e.g., publications to show that bridging is appropriate (this may be provided in an appendix);

- Testing procedures used to measure and obtain data on the surrogate tobacco product that may be used in lieu of data on the predicate product;
- Surrogate tobacco HPHC yields or quantities (these would not be needed when the new or predicate tobacco product is available for testing);
- Method validation reports of analytical testing (e.g., accuracy, repeatability, limit of detection, limit of quantification).

(Comment 56) One comment asks whether one product could be a surrogate for another product if the products contain an identical blend, but one product is wrapped in cellophane and the other is not.

(Response 56) While it may be possible to use a surrogate product in this instance, because the answer to this comment depends on more specific information than is provided, we recommend that for this or any other specific question related to the use of surrogates, the applicant contact the Agency.

(Comment 57) A few comments reference the comparison requirements (in § 1107.19) stating these unreasonably restrict the use of surrogate products and do not promote clarity and efficiency.

(Response 57) As we discuss in detail in preceding paragraphs, FDA is allowing the use of surrogate tobacco product data in specific scenarios and has provided a more robust description on how a surrogate can be utilized in an SE Report. Section 1107.19 does not place limitations on the type of scientific data an applicant may provide surrogate information for in lieu of the actual new or predicate tobacco product.

- *Statement of compliance with applicable tobacco product standards (§ 1107.18(i))*

In the proposed rule, we invited comment on how we should handle SE Reports that are pending at the time a final product standard issues with respect to the requirement that the SE Report include a statement of compliance with any applicable standard. We received some comments in response, which we discuss and respond to in the following paragraphs.

(Comment 58) One comment suggested that FDA should continue its review of the SE Report through final determination, and, if the product is determined to be substantially equivalent, FDA could condition the marketing of that product on the manufacturer establishing compliance with the product standard that went into effect while the SE Report was under review. The comment also states that, as part of issuing a standard, FDA should establish the process for bringing legally marketed products into compliance with the standard. Another comment suggests that applicants be permitted to modify their prior statements regarding compliance, and that compliance with the standard be considered during review of the pending SE Report.

(Response 58) We appreciate the information provided in response to our invitation to comment. FDA agrees with the comments that suggest that this issue should be considered as part of issuing a standard under section 907 of the FD&C Act (21 U.S.C. 387g). Additionally, the regulatory process that FDA must follow to issue a product standard under section 907 of the FD&C Act is lengthy and would provide applicants with notice of proposed requirements well in advance of any change becoming effective.

- *Compliance with part 25 (§ 1107.18(k))*

(Comment 59) Some comments urge FDA to either remove the requirement that manufacturers include an environmental assessment (EA) in their SE Reports or establish categorical exclusions for SE reports. The comments find the EA process unnecessarily burdensome without legitimate purpose. One comment objects that requiring EAs for deemed tobacco products that are still on the market is inconsistent with FDA's categorical exclusion for provisional SE Reports (those products on the market as of February 15, 2007) (see 80 FR 57531, September 24, 2015). The comment asserts FDA's different treatment of these categories of products is arbitrary and capricious. Other comments state that EAs are burdensome, with some noting greater difficulty for cigar manufacturers, and that FDA could alleviate some of these costs by allowing multiple products to be addressed in one EA or allowing the use of EA-specific master files for all products manufactured at the same facility.

(Response 59) We disagree with the assertion that the requirement of EAs is unnecessarily burdensome. FDA is required to examine the environmental impacts of issuing marketing orders under the National Environmental Policy Act of 1969 (NEPA) (FDA's implementing regulations are at Title 21 CFR, part 25). Part 25 requires EAs as a means of assessing the potential environmental impacts from tobacco products, which may present environmental issues during manufacturing (e.g., release of chemicals), use (e.g., smoke and aerosol may impact air quality), and disposal (e.g., litter, which persists in the environment and is toxic to different organisms). Per § 25.20, an EA is normally required for the issuance of an SE order, except that provisional SE reports that receive an SE order are categorially excluded under § 25.35(a). SE Reports for which an NSE is issued are also categorically excluded from having an EA under § 25.35; however, that outcome is not known until review of an SE Report is complete.

FDA also disagrees with the assertion that the requirement of EAs for deemed tobacco products still on the market is inconsistent, arbitrary, or capricious in comparison to the requirements for provisional products. In issuing the categorical exclusion for provisional

products, FDA provided an estimate of the environmental impacts of all FDA-regulated tobacco products on the market, including products marketed after February 15, 2007, and before March 22, 2011, and pre-Existing tobacco products (tobacco products that were commercially marketed in the United States as of February 15, 2007) (79 FR 3742 at 3746). FDA currently lacks the information to conduct such an analysis for deemed tobacco products still on the market. Unlike provisional products, deemed tobacco products include products whose environmental impacts are largely unknown, with the potential to result in greater or different impacts on the environment compared to other tobacco products. Because there is no basis for such a categorical exclusion at this time, NEPA and its implementing regulations require FDA to examine the potential environmental impacts from the issuance of an SE order; therefore, EAs are required for deemed tobacco products to comply with NEPA.

We disagree with the suggestions that a single EA be submitted for multiple products or that an EA-specific master file be permitted. Additionally, FDA is required by regulation to evaluate the environmental impact individually from one proposed action (§ 25.40(a)). An aggregated impact from multiple products is not sufficient under NEPA to determine whether the individual proposed action has a significant impact on the human environment.

- *Certification statement (§ 1107.18(l))*

(Comment 60) Some comments assert that FDA has no authority to impose the certification requirement or that it invites imprecision and falsification particularly when certifying that characteristics are identical without supporting test data. Other comments suggest there is no need for this "additional assurance." Two comments suggest that an applicant should be permitted to submit a certification stating that all characteristics of the new and predicate tobacco products are identical except for those identified. Alternatively, other comments support the certification approach and request that we permit applicants of currently pending SE Reports to submit such a certification without waiting for the final rule to become effective. One

comment states that any certification that some or all characteristics are identical must be fully supported by actual test data.

(Response 60) We disagree that FDA does not have the authority to impose the certification requirement, that it invites imprecision or falsification, or is unnecessary. Section 905(j)(1) of the FD&C Act authorizes FDA to issue regulations prescribing the form and manner of SE Reports, and we have included this requirement based on that authority. Notably, as some comments indicate, these certifications can help minimize the burden on applicants by providing an opportunity to certify when characteristics are identical (§ 1107.18(*l*)(2)). With respect to the concern related to ensuring there is underlying support for a certification, the certification is intended in part to ensure that an applicant is prepared to support their SE Report with further information, if needed (for example, the certification in § 1107.18(*l*)(2) provides that the company "will maintain records to support the comparison information in § 1107.19 that substantiate the accuracy of this statement"). The certification also is intended to provide FDA with assurance that the applicant has fully considered the SE Report and its contents, believes there is a basis for making the findings required by section 910(a)(2) of the FD&C Act, and understands the potential consequences of submitting false information to the U.S. Government.

Thus, contrary to what some of the comments suggest, the certification is an important, but also simple, means of helping ensure that the authorized representative is aware of and understands the recordkeeping requirements, that the submission is truthful and accurate, and the representative is authorized to submit the SE Report on behalf of the applicant. For a certification under § 1107.18(*l*)(2), the certification also helps ensure that the authorized representative is aware of and understands that, in lieu of providing data for each characteristic of the new and predicate tobacco products, the applicant is choosing to certify that the characteristics of the products are identical and that records will be maintained to support this determination. With respect to the comment that requests FDA permit this for pending SE Reports, as explained in preceding paragraphs, this rule does not apply to pending submissions.

3. Comparison Information (§ 1107.19)

Proposed §1107.19 set out the comparison information that would be required in an SE Report. It also set forth the manner in which the comparison section of the SE Report would be required to be organized, and explained that applicants who make a comparison of a new product to a predicate product may also need to provide information to demonstrate that the new tobacco product is substantially equivalent to the original predicate tobacco product. Following our consideration of the comments, which we describe and respond to in detail in this section, we are clarifying in this preamble and in changes to the codified that § 1107.19 applies to "different characteristics" SE Reports. "Same characteristics" SE Reports do not need to include the information in this section. In reviewing an SE Report, FDA may request additional information if needed to make an SE determination.

On our own initiative, we have revised the introductory text in § 1107.19 so that it no longer states "The comparison section of the SE Report must be organized in the following manner" as not all of the subsections require information to be submitted in an SE Report, and instead added "as described in this section." Following our consideration of comments and based on our increased experience reviewing SE Reports, we are finalizing with changes § 1107.19(a) (comparison of product design). These changes include the addition of design parameters for cigars, pipes, waterpipes, ENDS, and heated tobacco products, as described in detail in the product design paragraphs that follow.

In addition, we have made clarifications in § 1107.19(c) (product composition), including replacing "material" with "ingredient" in paragraph (c)(2)(iv) due to a typographical error; adding examples of the type of tobacco to be identified and striking "grade and variety" in paragraph (c)(3)(i) because tobacco grading is not uniform throughout the industry, which reduces the utility of this information in application review, and FDA does not need to characterize the tobacco type to the level of detail of tobacco variety for the purposes of an SE evaluation; adding a requirement that information on the type of curing method be submitted as

paragraph (c)(3)(ii) because the curing method is known to influence the formation of TSNAs and other select HPHCs and this information will allow FDA to fully characterize the tobacco (Refs. 13 and 14); adding "of each type" following quantity in paragraph (c)(3)(iii), and striking proposed paragraph (c)(3)(iii) to clarify we need this for each type of tobacco since many tobacco products are made from blends of different tobacco types.

To § 1107.19(d)(1)(ii)(F) we have added a requirement that full validation reports for each analytical method be included because, as noted in the earlier discussion in this rule, this information is needed to ensure the method is fit for purpose and the measured values can be accurately compared between a new and predicate tobacco product.

In addition, we added that reference product datasets be included (if applicable) in § 1107.19(d)(1)(ii)(J). A reference product is a product of known physical and chemical composition and is typically accompanied by a Certificate of Analysis that states the attributes of the reference product. A suitable reference product is one that is compositionally and functionally representative of the test samples in the study, and laboratories may use a reference product for proficiency testing to demonstrate that the laboratory is capable of accurately measuring tobacco chemicals of interest and as a control sample during instrument calibration, method validation, and sample analysis. Thus, reference product datasets are used to demonstrate that the test results obtained from testing of tobacco products are reliable. Because of the addition of reference product datasets to the final rule, we have renumbered proposed § 1107.19(d)(1)(ii)(J) to § 1107.19(d)(1)(ii)(K). In the final rule, we also are adding to § 1107.19(d)(1)(ii)(K) "Test data for combusted or heated tobacco products must reflect testing conducted using both intense and nonintense smoking or aerosol-generating regimens, where established" (Refs. 15 and 16). The proposed rule explained that for combusted tobacco products constituent smoke yields from the new and predicate tobacco products would need to be determined using intense and nonintense smoking regimens, but the proposed codified did not specifically reference these regimens (see 84 FR 12740 at 12763). Following our consideration

of comments on this issue (see later paragraphs in this section for a discussion of comments), we added codified text to ensure the understanding that this is required for these products. Because heated tobacco products present issues similar to combusted tobacco products, the final rule also specifies that test data for heated tobacco products reflect testing conducted using both intense and nonintense smoking or aerosol-generating regimens, where established. The final rule also now includes a § 1107.19(d)(1)(ii)(L) that clarifies that the applicant must include in the SE Report a complete description of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable.

In addition, we have reorganized and modified proposed § 1107.19(e) for clarity. We also added a requirement for information on the heat treatment process (if applicable), which is a tobacco processing method that could potentially reduce the microbial load of the tobacco product and result in lower levels of carcinogenic TSNAs, thereby altering product composition (i.e., product characteristics) in § 1107.19(e)(2) (Refs. 17 and 18). For better organization, we moved the stability information in proposed § 1107.19(e) to § 1107.19(f); moved the testing information from proposed § 1107.18(h) to § 1107.19; and renumbered proposed § 1107.19(f) to § 1107.19(g) and proposed § 1107.19(g) to § 1107.19(h) in this final rule.

Following our consideration of comments, we are finalizing the stability testing in § 1107.19(f) with some changes. First, we are expanding the types of tobacco products that will need to submit information on stability and shelf life. The proposed rule would only have required stability testing information for smokeless tobacco products and tobacco products that contained fermented tobacco, including naturally fermented tobacco. As explained in the proposed rule, stability information is a particular concern with smokeless tobacco products and other tobacco products that contain fermented tobacco because the characteristics of these products can be affected by the manufacturing process, storage conditions, and length of time on a shelf.

Upon further consideration, the final rule will require information on stability and shelf life for all tobacco products, except RYO tobacco products and cigarettes that are not HTPs.[13] Information obtained through stability testing and shelf life is important for FDA to consider during its review to ensure that the tobacco products are microbiologically and chemically stable during storage and do not result in different questions of public health. Fermentation of tobacco (including natural fermentation) affects the microbial content, which could potentially affect TSNA content and product stability (Refs. 19-24). In addition, based on our experience, HTPs can contain high levels of humectants, which can affect product stability; therefore shelf life and stability information is required to support an SE report for HTPs. Humectants function to keep a product moist, thereby impacting the moisture content and water activity of the product, which in turn may impact microbial growth and product stability (Ref. 25).

Based on FDA's experience with cigarettes and RYO tobacco products under the SE pathway and because the vast majority of cigarettes and RYO tobacco products do not contain fermented tobacco, these products do not have the same stability concerns. However, we lack similar experience with more novel tobacco products, such as ENDS and HTPs, and thus need stability information for these types of products to determine whether there is a difference in microbial factors or HPHC quantities over time. The proposed rule did not specify that this information was needed for novel tobacco products because we did not expect many substantial equivalence reports to be submitted for novel tobacco products. In reviewing the PMTA rule and its stability requirements, though, we recognized the possibility that a novel product manufacturer may pursue authorization through the SE pathway and we wanted to make sure that both the PMTA and SE regulations would require applicants to provide the Agency with the necessary stability information. FDA believes information regarding these products' shelf life and stability over time is needed to ensure FDA fully understands the microbial and chemical

[13] See the discussion in section V.D.2, about how products should be categorized for purposes of SE review.

stability of the new and predicate tobacco products throughout their stated shelf life, and will thus have the needed information to make the SE determination.

Second, stability testing requirements have been updated to remove identification of microbiological organisms by genus and species and remove testing for pH, moisture content, nitrate and nitrite levels, and preservatives and microbial metabolic inhibitors. In addition, if a tobacco product does not have a defined shelf life, stability data will need to be provided over a specified amount of time with a justification for why that time period is appropriate.

Section 1107.19(f)(2) of the proposed rule (now § 1107.19(g)(2)) stated that, when an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: product design (§ 1107.19(a)); heating source (§ 1107.19(b)); materials and ingredients (§ 1107.19(c)); and other features (§ 1107.19(d)). In addition, to demonstrate that a new tobacco product with different characteristics is substantially equivalent, an applicant must also explain why any difference in the manufacturing process between the new tobacco product and the predicate tobacco product does not raise different questions of public health (§ 1107.18(e)). Similarly, for smokeless tobacco products, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not raise different questions of public health (§ 1107.19(e)). In the final rule, we have updated this subsection to remove repetitive language (i.e., "with different characteristics"), add clarifying language ("would not change the characteristics of the new tobacco product such that the new tobacco product could" and "cause the new tobacco product to"), and after "smokeless tobacco" add "and tobacco products that contain fermented tobacco as these tobacco products have similar stability considerations."

We have also updated § 1107.19(i) to reflect the updated definition of predicate tobacco product, as described in the definitions section of this final rule.

- *Product design (§ 1107.19(a))*

In the following paragraphs, we describe in more detail the changes to § 1107.19(a)and we describe the comments submitted on § 1107.19(a) and our responses to those comments.

We have revised § 1107.19(a) so that it does not require test data, target specifications and range limits be submitted in all instances, as the proposed rule would have required. Instead, § 1107.19(a) requires that SE Reports include test data (including test protocols, quantitative acceptance criteria, data sets (i.e., measured values), and a summary of the results) only when the target specification or range limits of the new tobacco product differ from the predicate tobacco product. We have also clarified that test data would need to be submitted for both the new and predicate tobacco products. Additionally, FDA has clarified that for tobacco cut size or particle size, when target specifications and range limits are not available, the following alternative information may be submitted in place of this information: a description of the tobacco cutting process (including a complete description of the milling, cutting, and sifting process; the control parameters of the miller or cutter; and any sift specifications) or the measured particle size distribution for the new and predicate tobacco products. This alternative may be used, for example, if an applicant does not set target specifications or range limits for tobacco cut size. In this case, they could submit information about the tobacco cutting process of the new and predicate tobacco products to demonstrate that the products are substantially equivalent.

Applicants may also choose to submit the necessary design parameter information using a Manufacturing Data Sheet Specification (MDSS) document. The MDSS is a document typically maintained by manufacturers, describing all the parameters that are controlled by the manufacturer during manufacture of their tobacco products. However, there will be cases where the design parameters on the MDSS will not directly translate into one of the product-specific design parameters required in § 1107.19. In these cases, additional information would need to be submitted to provide the complete characterization necessary. Additionally, FDA will not require test data for all parameters for which target and range are required. For example, for parameters

that are observational (e.g., number of waterpipe holes), FDA would not seek test data on that parameter. Also, some design parameters are machine settings (e.g., tobacco cut size), calculated (e.g., denier per filament), provided by suppliers (e.g., Certificate of Analysis for base paper porosity), or can be extrapolated from other design parameter test data (e.g., filter pressure drop test data is more informative than filter length test data). FDA has clarified alternative terminology for "porosity" understanding that applicants may refer to this term as "permeability" for several design parameters, as well as adding units of measure for several design parameters.

Following our review of comments, we have revised the tables of design parameters required for certain product categories as described here:

Cigarettes: As discussed in section V.D.2 above, tobacco products that meet the definition of cigarette but are heated tobacco products should be categorized as heated tobacco products (HTPs) for purposes of SE review. Accordingly, this section discusses cigarettes that are not HTPs. Section 1107.19(a) has changed certain proposed requirements under target specification and range. These changes include: (1) removal of the proposed requirement for applicants to provide cigarette draw resistance as FDA determined that requiring this as distinct parameter was unnecessary and not as informative as filter pressure drop because draw resistance could be modified by the user by puffing more or less intensely; (2) removal of cigarette paper base paper basis weight as it provides duplicative information that is already captured by the submission of ingredient levels (e.g., a higher basis weight might be due to the inclusion of more cellulose and more calcium carbonate); (3) addition of tobacco cut size as this parameter has an influence on the chemical concentration in the combusted portion of the cigarette, combustion temperature, and affects the particle size and distribution of particles; (4) FDA has clarified terminology for cigarette paper band porosity, as applicants may refer to this term as permeability, and also provide an alternative to providing cigarette paper band porosity or permeability. Band diffusivity, while not preferred, is an acceptable alternative if it is currently not part of an applicant's practice to specify cigarette paper band porosity. Regardless of whether

porosity or diffusivity is specified, the same parameter must be provided for both the new and predicate tobacco products to conduct a meaningful comparison. While there are minor differences (porosity is more relevant during active puffing, whereas diffusivity is more relevant during smoldering), the addition of diffusivity as an alternative parameter allows flexibility to applicants who do not directly measure porosity or permeability while still providing FDA with the information it needs to make the substantial equivalence finding (Ref. 26).

FDA has revised certain proposed parameters for test data which include: (1) removal of puff count as this was duplicative of information that an applicant would submit with smoke constituent data because puff count is determined in a smoking machine using either the International Organization for Standardization or Health Canada Intense smoking regimen or other applicable regimen (Refs. 27 and 28); (2) removal of cigarette draw resistance as explained above; (3) removal of cigarette paper base paper basis weight as explained above; (4) addition of tobacco filler mass as this has a direct influence on smoke constituents (Ref. 29); and (5) the option to provide oven volatiles instead of moisture as this provides similar information to FDA (Ref. 30)[14] and allows the applicant flexibility to provide either parameter based on the specific manufacturing processes they employ.

Smokeless Tobacco: Section 1107.19(a) has changed certain proposed requirements under target specification and range. These changes include: (1) removal of portion thickness as it is an unnecessary parameter because it is the pouch effective area that may result in an increase of the release level of nicotine, unprotonated nicotine, and could affect TSNA levels and the pouch effective area can be calculated from other required design parameters, i.e., pouch length and pouch width; (2) addition of pouch material thickness as this parameter influences the

[14] Please note that the term "moisture," has widely varying and conflicting definitions and terminology in use within the tobacco industry. It is common for "moisture" or "moisture content" to be used to refer to water content of a material but in relation to the tobacco industry it is necessary to differentiate between "moisture" as water content and "moisture" as oven volatiles. https://www.coresta.org/sites/default/files/technical_documents/main/PTM-CTR_MoistureWaterOvenVolatiles_July2014%282%29.pdf.

release level of nicotine and can affect TSNA levels[15]; (3) addition of nicotine dissolution rate because it is a measure of how much free nicotine a user could be exposed to and differences in nicotine dissolution can have an impact on addiction and nicotine uptake (Refs. 31, 32, 85); and (4) clarification of requiring certain parameters "if applicable" for portioned product properties (i.e., portion length, portion width, and portion mass, "if applicable" has been removed) because these parameters are needed for all portioned smokeless products. However, not all portioned products are pouched, so the pouch-specific properties should only be reported if applicable, and thus FDA has added "if applicable" to pouch material porosity or permeability and pouch material basis weight.

Roll-your-own tobacco, rolling papers: Section 1107.19(a) has changed a proposed requirement under target specification, range, and test data. This change includes the option to provide diffusivity in lieu of cigarette paper band porosity (also described as permeability) for the reasons explained above under *Cigarettes*.

Roll-your-own tobacco, non-filtered tubes: Section 1107.19(a) has changed certain proposed requirements under target specification and range. These changes include the addition of: (1) clarification of terminology changing "total mass (mg)" to "tube mass (mg);" (2) the option to provide tube diameter as an alternative to tube circumference as FDA is able to obtain the information necessary from other required design parameters; and (3) the option for the applicant to provide diffusivity in lieu of cigarette paper band porosity or permeability as described above. This alternative is also provided under test data for this product category.

Roll-your-own tobacco, filtered tubes: Section 1107.19(a) has changed certain proposed requirements under target specification and range. These changes include the addition of: (1) clarification of terminology changing "total mass (mg)" to "tube mass (mg);" (2) the option to

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[15] See, e.g., Gale, N., G. Errington, and K. McAdam, Group Research & Development, British American Tobacco, "Effects of Product Format on Nicotine and TSNA Extraction from Snus Pouches," Presentation at the 67th Tobacco Science Research Conference, Williamsburg, VA, September 15-18, 2013. Available at: https://www.researchgate.net/publication/299854728_Effects_of_Product_Format_on_Nicotine_and_TSNA_Extraction_from_Snus_Pouches.

provide tube diameter as an alternative to tube circumference as FDA is able to obtain the information necessary from other required design parameters ; (3) the option for the applicant to provide filter efficiency as an alternative to denier per filament, total denier, or filter density (Ref. 33); and (4) the option for the applicant to provide diffusivity in lieu of cigarette paper band porosity or permeability as described above. These alternatives (filter efficiency and diffusivity) are also provided under test data for this product category.

Roll-your-own tobacco: Section 1107.19(a) has changed certain proposed requirements under target specification, range, and test data. This change includes the removal of the requirement for the applicant to provide filler mass as this is provided as part of unique identification of the tobacco product under § 1107.18.

In addition, in the proposed rule, we invited comments and information on the parameters that may be needed to support an SE Report for tobacco products that were not specifically included in the proposed rule, such as cigars and ENDS. Based on the comments and information we received, we have added design parameters to § 1107.19(a) for cigar tobacco products, pipe tobacco products, waterpipe tobacco products, ENDS tobacco products, and heated tobacco products, as described in the following paragraphs.

Cigars. Cigarettes (outside the category of heated tobacco products) and cigars are generally similar in design and principles of operation as they are both cylinders filled with a blend of processed tobacco that is generally smoked. Both are generally lit with a fire source, which burns the tobacco as the user inhales at one end; thus, they are consumed and deliver nicotine in a similar manner. A main difference between cigarettes and cigars is that cigars are either wrapped in a tobacco leaf (wrapper and binder) or a material containing tobacco, whereas non-HTP cigarettes are wrapped in paper (cigarette paper) or a material that does not contain tobacco. Additionally, cigars come in a wider variety of sizes and may be thicker in diameter and contain more tobacco filler than cigarettes. Despite these differences, for both types of tobacco products, no matter the size, air is pulled through the tobacco column, which aids in tobacco

combustion and nicotine delivery. Cigarette paper commonly has an established porosity or permeability, that is set during manufacturing, while cigar wrapper properties are based on the tobacco used as the wrapper. Although cigars and cigarettes may be wrapped in different materials, both cigar wrappers and binders, as well as cigarette papers, have inherent permeabilities/porosities, which may affect smoke constituent yields. Cigars may be filtered (containing filter tow or other materials), unfiltered, or unfiltered with tips made of wood or plastic, while most cigarettes have filters (containing filter tow) and do not contain tips. If a cigar does contain a filter, it will be similar to cigarette filters and contain tow. Based on FDA's experience with cigarettes, many design parameters required to assess public health impacts for cigarettes will also be needed to assess public health impacts for cigars. The following paragraphs describe in more detail the required parameters for each subcategory of cigars.

Filtered, sheet-wrapped cigars: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize filtered, sheet-wrapped cigars and how changes to these parameters may impact public health, as described next:

- Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 34).
- Cigar puff count can directly affect smoke constituent yields (Ref. 34).
- Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 35).
- Tobacco filler mass may affect smoke constituent yields (Ref. 34).
- For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 37).
- For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder width and wrapper length may directly influence the area through which air is permitted to enter

the tobacco column, which, in turn, may affect puff count and smoke constituent yields.

- Cigar wrapper porosity may affect smoke constituent yields (Refs. 37 and 38).
- For cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 39 and 40). Similarly for cigars, the tobacco rod density may modify burn properties and smoke constituent yields.
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for cigars, the tobacco moisture or oven volatiles may affect puff count.
- For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.
- For cigarettes, the band porosity may affect smoke constituent yields (Ref. 43). Similarly for cigars, the wrapper or binder band porosity or permeability may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the paper during active puffing.
- For cigarettes, the band width may affect smoke yields (Ref. 44). Similarly for cigars, the wrapper band width and binder band width may affect ventilation and, in turn, smoke constituent yields.
- For cigarettes, the band space may affect puff count (Ref. 45). Similarly for cigars, the wrapper band space and binder band space may affect ignition propensity and, in turn, puff count.
- For cigarettes, the filter parameters can impact smoke yields (Ref. 33). Similarly for cigars, the filter diameter, filter mass, and filter tow crimping index, denier per filament, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields.

- For cigarettes, the filter pressure drop affects smoke yields (Ref. 46). Similarly for cigars, the filter pressure drop may affect smoke constituent yields.
- For cigarettes, tipping paper length may affect smoke constituent yields (Ref. 47). Similarly for cigars, the tipping paper length may affect smoke constituent yields.
- Ventilation may affect smoke constituent yields (Ref. 34).
- For cigarettes, the diameter can affect the smoke yields (Ref. 46). Similarly for cigars, the cigar maximum and minimum diameter may affect rod density, which modifies the burn properties and smoke yields; FDA needs this information to characterize the diameters as shapes of cigars can differ with the tips being narrower than the center of the cigar. This may result in multiple rod densities used to test the smoke and influence smoke yields depending on what part of the cigar is tested.
- For cigarettes, the paper porosity may affect smoke constituents (Ref. 43). Similarly for cigars, the binder porosity may affect or may further limit air flow into and out of the cigar which may affect smoke yields.

Unfiltered, sheet-wrapped cigars: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize unfiltered, sheet-wrapped cigars and how changes to these parameters may impact public health, as described next:

- Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 34).
- Cigar puff count can directly affect smoke constituent yields (Ref. 34).
- Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 35).
- Tobacco filler mass may affect smoke constituent yields (Ref. 34).
- For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 37).

- For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder width and wrapper length may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.
- Cigar wrapper porosity may affect smoke constituent yields (Refs. 37 and 38).
- For cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 39 and 40). Similarly for cigars, the tobacco rod density may modify burn properties and smoke constituent yields.
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for cigars, the tobacco moisture or oven volatiles may affect puff count.
- For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.
- For cigarettes, the band porosity may affect smoke constituent yields (Ref. 43). Similarly for cigars, the wrapper or binder band porosity or permeability may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the paper during active puffing.
- For cigarettes, the band width may affect smoke yields (Ref. 44). Similarly for cigars, the wrapper and binder band width may affect ventilation and, in turn, smoke constituent yields.
- For cigarettes, the band space may affect puff count (Ref. 45). Similarly for cigars, the wrapper and binder band space may affect ignition propensity and, in turn, puff count.
- Cigar tip mass, length, and inner diameter dimensions directly influence the overall cigar draw resistance and in turn, puff count (Ref. 48).

- For cigarettes, the diameter can affect the smoke yields (Ref. 46). Similarly for cigars, the cigar maximum and minimum diameter may affect rod density, which modifies the burn properties and smoke yields; FDA needs this information to characterize the diameters as shapes of cigars can differ with the tips being narrower than the center of the cigar. This may result in multiple rod densities used to test the smoke and influence smoke yields depending on what part of the cigar is tested.
- For cigarettes, the paper porosity may affect smoke constituents (Ref. 43). Similarly for cigars, the binder porosity may affect or may further limit air flow into and out of the cigar which may affect smoke yields.

Unfiltered, leaf-wrapped cigars: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize unfiltered, leaf-wrapped cigars and how changes to these parameters may impact public health, as described next:

- Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 34).
- Cigar puff count can directly affect smoke constituent yields (Ref. 34).
- For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar binder and wrapper length and wrapper width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.
- Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 35).
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for cigars, the tobacco moisture or oven volatiles may affect puff count.

- For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 37).
- For cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 39 and 40). Similarly for cigars, the tobacco rod density may modify burn properties and smoke constituent yields.
- For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.
- Tobacco filler mass may affect smoke constituent yields (Ref. 34).
- For cigarettes, the diameter can affect the smoke yields (Ref. 46). Similarly for cigars, the cigar maximum and minimum diameter may affect rod density, which modifies the burn properties and smoke yields; FDA needs this information to characterize the diameters as shapes of cigars can differ with the tips being narrower than the center of the cigar. This may result in multiple rod densities used to test the smoke and influence smoke yields depending on what part of the cigar is tested.

Cigar filler[16]*:* Section 1107.19(a) describes the design parameters that must be contained in an SE Report to fully characterize cigar filler and how changes to these parameters may impact public health, as described next:

- For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for cigars, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for cigars, the tobacco moisture or oven volatiles may affect puff count.

[16] These design parameters are for an SE Report where "cigar filler" is the new tobacco product (not when cigar filler is a component or part of a cigar or other tobacco product).

Cigar component[17]: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize a cigar component and how changes to these parameters may impact public health, as described next:

- For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper length and width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.
- For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for cigars, the cigar wrapper basis weight may affect puff count and smoke constituent yields (Refs. 36 and 37).
- Cigar wrapper porosity may affect smoke constituent yields (Refs. 37 and 38).

Pipe. Cigarette tobacco and pipe tobacco are similar, as they are both processed tobacco that is cut, milled, and sifted before ingredients are added to control for tobacco moisture and taste. Therefore, tobacco parameters for a cigarette can be extrapolated to tobacco parameters for a pipe. Additionally, the filter in a pipe is similar to a filter in a cigarette, as they both contain tow and the length of the filter can determine the amount of suction a smoker needs to apply to the tobacco product to draw smoke through (filter pressure drop). Furthermore, the filter in a pipe can affect the filter efficiency just as a cigarette filter would. Therefore, filter pressure drop and filter parameters for a cigarette can be extrapolated to the filter parameters for a pipe. Based on FDA's experience with cigarettes, many design parameters required to assess public health impacts for cigarettes will also be needed to assess public health impacts for pipes. The following paragraphs describe in more detail the required parameters for each subcategory of pipes.

[17] These design parameters are for an SE Report where a "cigar component" is the new tobacco product (not when the cigar component is a component or part of a cigar or other tobacco product).

Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize a pipe and how changes to these parameters impact public health, as described next:

- The bowl chamber inner and outer diameters allow FDA to calculate the chamber wall thickness. A thicker wall will lead to a cooler smoke and makes it less likely the user will burn themselves when holding the chamber. Additionally, the chamber inner diameter will affect temperature and tobacco capacity, meaning the greater the pipe surface area, the more leaf can be burned at once, and with increased temperature, as we have learned from our experience with other types of tobacco products (e.g., cigarettes), this will affect smoke constituents.
- The bowl chamber hole shape is important to characterize the pipe as this may affect the airflow and tobacco temperatures, which, as we have learned from our experience with other types of tobacco products (e.g., cigarettes), affects the burn rate and smoke constituents delivered.
- The bowl chamber volume affects the burn rate and temperature, which, as we have learned from our experience with other types of tobacco products (e.g., cigarettes), dictates the smoke constituents delivered to users.
- The draught hole allows the user to pull air through the tobacco to their mouth. The diameter of the draught hole affects the resistance to draw which, as we have learned from our experience with other types of tobacco products (e.g., cigarettes), can impact nicotine and other toxicant delivery to the user.
- The draught hole dimensions and geometry may affect the airflow and oxygen available at the burning tobacco for the chemical reaction and, as we have learned from our experience with other types of tobacco products (e.g., cigarettes), can affect smoke constituent yields.

- The location of the draught hole can affect airflow and tobacco temperatures, which, as we have learned from our experience with other types of tobacco products (e.g., cigarettes), affects the burn rate and smoke constituents delivered.
- The stem of a pipe delivers smoke from the bowl to the user's mouth. The length of the stem may affect the smoke temperature, which may affect how the product is consumed, while the width of the stem may affect resistance to draw which, as we have learned from our experience with other types of tobacco products (e.g., cigarettes), can impact toxicant delivery to the user.
- The shank of a pipe similarly may affect the smoke temperature (length) and resistance to draw (diameter), which, as we have learned from our experience with other types of tobacco products (e.g., cigarettes), can impact nicotine and other toxicant delivery to the user.
- For cigarettes, the filter pressure drop affects smoke yields (Ref. 46). Similarly for pipes, the pressure drop through the air valve can affect nicotine and other toxicant delivery to the user. Air flow through an air valve can affect tobacco burn rate and tobacco temperatures which in turn, may affect smoke constituent delivery to the user.
- Some pipes may come with a filter. For cigarettes, filter diameter, denier per filament, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 33). Similarly for pipes, the filter efficiency, filter pressure drop, and filter length may affect smoke constituent yields.

Pipe tobacco. Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize pipe tobacco and how changes to these parameters may impact public health:

- For cigarettes, the tobacco cut size may result in more particulate matter (Ref. 42). Similarly for pipes, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for pipes, the tobacco moisture or oven volatiles may affect puff count.

Waterpipes: Cigarette tobacco and waterpipe tobacco are similar, as they are both processed tobacco that is cut, milled, and sifted before ingredients are added to control for tobacco moisture and taste. Therefore, tobacco parameters for a cigarette can be extrapolated to tobacco parameters for a waterpipe. Additionally, the length of the waterpipe stem affects the pressure drop in the waterpipe in a similar way as the length of the filter and filter tow causes a filter pressure drop in a cigarette: both determine the amount of suction a smoker needs to apply to the tobacco product to draw smoke through. Therefore, filter pressure drop for a cigarette can be extrapolated to the pressure drop of a waterpipe. Based on FDA's experience with cigarettes, many design parameters required to assess public health impacts for cigarettes will also be needed to assess public health impacts for waterpipes. The following paragraphs describe in more detail the required parameters for each subcategory of waterpipes.

Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize waterpipes and how changes to these parameters may impact public health, as described next:

- Hose dimensions (length and diameter) are directly proportional to air infiltration and affects toxicant yields (Ref. 49).
- Hose material may affect hose permeability, which may affect smoke constituent yields (Ref. 49).
- Water filtering efficiency is directly proportional to mainstream smoke and can increase exposure to HPHCs (Ref. 50).

- For cigarettes, the filter pressure drop affects smoke yields (Ref. 46). Similarly for waterpipes, the pressure drop may result in differences in the difficulty of pulling air through the waterpipe and, in turn, affect smoke constituent yields.
- Waterpipe components or parts, including stem, bowl, windscreen (foil), and purge valve, impact puffing behavior and toxicant exposure; therefore, the foil dimensions and ventilation may affect smoke constituent yields (Ref. 51).
- The shape and size (diameter and volume) of the base can affect the pressure drop or difficulty of pulling air through the waterpipe hose (Ref. 51).
- The head dimensions (height, top diameter, bottom diameter, volume, and number of holes) affect how long a smoke session lasts by controlling how much tobacco can be used during a session. Head dimensions can also affect airflow beneath and through the tobacco to make heat transfer more effective, prolonging smoking sessions (Ref. 51).
- The head materials could aid in heat transfer, prolonging the heating of the tobacco and causing the tobacco to reach temperatures that affect smoke yields (Ref. 52).

Waterpipe heating source: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize a waterpipe heating source and how changes to these parameters may impact public health, as described next:

- When combusted, heating sources such as charcoal or wood cinders expose the user to high yields of toxicants such as carbon monoxide and polycyclic aromatic hydrocarbons. Therefore, the heating source mass, density, and temperature may affect smoke constituent yields (Ref. 53).

Waterpipe filler: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize waterpipe filler and how changes to these parameters may impact public health, as described next:

- For cigarettes, the tobacco cut size may result in more particulate matter (Refs. 41 and 42). Similarly for waterpipe filler, the tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter. Finer tobacco cut size may result in a decrease in filling power and in turn, a larger amount of tobacco in the bowl.
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for waterpipe filler, the tobacco moisture or oven volatiles may affect puff count. Moisture contributes to packing density, thus decreasing void volume.

Waterpipe foil: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize waterpipe foil and changes to these parameters may impact public health, as described next:

- Waterpipe components or parts, including the windscreen (foil) impact smoke's puffing behavior and toxicant exposure. Therefore, the foil dimensions such as length, width, diameter, and foil thickness may affect smoke constituent yields (Ref. 51).
- The aluminum foil perforation pattern (diameter and number of holes) impacts the path of hot gases through the tobacco mixture, which may affect smoke constituent yields (Ref. 51).

Waterpipe head: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize a waterpipe head and how changes to these parameters may impact public health, as described next:

- Waterpipe components or parts, including stem, bowl, windscreen (foil), and purge valve, impact puffing behavior and toxicant exposure; therefore, the foil dimensions and ventilation may affect smoke constituent yields (Ref. 51).

ENDS: Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize ENDS and how changes to these parameters may impact public health, as described next:

- The air flow rate of the ENDS can affect the coil/heating element temperature, e-liquid consumption, and aerosol characteristics such as particle number concentration, count median diameter, and particulate matter (PM)2.5, which impact aerosol exposure (Ref. 54).
- Coil/heating element resistance may affect overall heating element resistance, thereby influencing heating element temperature. The coil/heating element's resistance, material and the voltage[18] determine the current flow and heating element temperature. Because the coil/heating element temperature is not constant, coil/heating element resistance can be used to characterize the coil temperature over time. The heating element temperature and temperature duration may affect toxicant emissions and nicotine delivery (Refs. 55-59).
- Coil/heating element resistance and battery output voltage determine power delivery unit (PDU) wattage. PDU wattage determines the amount of heat produced by the atomizer. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 57 and 59).
- An increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 58).
- The temperature of the coil/heating element can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in coil/heating element temperature can increase HPHC levels in the aerosol, therefore, maximum coil/heating element temperature and temperature control deviation from this

[18] Voltage, current, and resistance are used to ensure the battery and the ENDS are operating within the "normal operating range." The battery manufacturer sets the normal range of the voltage and current. Understanding the resistance allows FDA to assess whether the coil is drawing more current than the battery is designed for.

maximum coil/heating element temperature can affect toxicant emissions and nicotine delivery (Refs. 56-59).

- Number of coils/heating element present can affect overall atomizer resistance and distribution of heat dissipation (Ref. 60).
- The position of the coil/heating element can increase the possibility of dry puff conditions and subsequent increased toxicant emissions (Ref. 57).
- Atomizer and cartridge components of e-cigarettes may be heated repeatedly and aerosolized and can contribute to increased toxicant emissions (Ref. 55).
- Puff count can differ depending on other puff topography (e.g., puff duration and puff flow rate), e-cigarette and atomizer design, and e-liquid parameters. Puff count can also affect total puff volume, which in turn can affect total toxicant emissions (Ref. 61). In addition, information on the puff count of ENDS helps FDA assess how the product compares with other products.
- E-liquid capacity of the atomizer tank/cartridge can affect total puff volume, which in turn can affect total toxicant emissions (Refs. 61 and 62).
- Battery/PDU voltage or voltage operating range may affect the heating element temperature, thereby affecting toxicant emissions and nicotine delivery (Refs. 56-59).
- Battery wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 57 and 59).
- Coil/heating element resistance and battery output voltage determine PDU wattage. PDU wattage determines the amount of heat produced by the atomizer. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 57 and 59).
- PDU wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 57 and 59).

- The temperature of the coil/heating element can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in coil/heating element temperature can increase HPHC levels in the aerosol, therefore, maximum coil/heating element temperature and temperature control deviation from this maximum coil/heating element temperature can affect toxicant emissions and nicotine delivery (Refs. 56-59).
- Coil/heating element resistance, number of coils/heating element, coil/heating element gauge, and coil/heating element configuration may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery (Refs. 55-59).
- Battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63).
- Battery power impacts the delivery of nicotine and the total emissions of volatile aldehydes (Refs. 64 and 65).
- Battery and PDU voltage impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 65).
- The draw resistance of the ENDS impacts the ease of drawing air into the ENDS to produce aerosol, which can affect nicotine and other toxicant delivery to the user (Ref. 66). For cigarettes, we evaluate filter pressure drop since it is more informative than draw resistance; however, for ENDS, there is no filter pressure drop or other similar parameter that could be used in place of draw resistance.

- PDU current cutoff is an electrical cutoff and a safety feature, that interrupts electric current when a specific condition is met (temperature, current, etc.) to protect the user. (Refs. 55 and 63).
- Inhaled aerosol temperatures can be damaging or uncomfortable to users who inhale aerosol above a certain temperature (Ref. 67).

E-liquid. Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize e-liquids and how changes to these parameters may impact public health, as described next:

- The e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 61 and 62).
- Aerosol parameters such as particle number concentration, count median diameter, and PM2.5 are used to characterize the amount and size of particles to which the user is exposed. Epidemiological and clinical studies have shown that exposure to large amounts of small particles can impair lung function and is correlated with cardiovascular disease (Refs. 68 and 69).
- E-liquid viscosity and boiling point impact the proportion of nicotine that is aerosolized (Ref. 70). E-liquid viscosity can also affect the e-liquid absorbency through the wick and wicking rate, possibly leading to dry puff conditions and increased toxicant emissions. Also, the e-liquid viscosity can affect the electronic cigarette nicotine and other toxicant delivery to the user (Refs. 60 and 61).
- The e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 61 and 62).

Heated tobacco products (HTP): HTPs currently sold in global markets can function in ways that are similar to products in other product categories. For example, some HTPs can function like ENDS products by aerosolizing e-liquids or using a battery and PDU to power the product. Other HTPs can contain tobacco filler, like a non-HTP cigarette or cigar, but are heated

instead of combusted. For these reasons, the properties of HTPs vary widely but are comparable to the properties of other tobacco product categories. Based on FDA's experience with other similarly characterized tobacco products, many design parameters required to assess public health impacts for those products will also be needed to assess public health impacts for HTPs. The following paragraphs describe in more detail the required parameters for each subcategory of HTPs.

Section 1107.19(a) includes the design parameters that must be contained in an SE Report to fully characterize HTPs and changes to how these parameters may impact public health, as described next.

- For cigars, the length, diameter, and mass can affect smoke constituent yields (Ref. 35). Similarly for HTPs, dimensions (mass, length, width, height, and diameter) can directly affect the amount of tobacco that is heated and, in turn, affect smoke constituent yields.
- For ENDS products, the draw resistance can affect nicotine and other toxicant delivery to the user (Ref. 66). Similarly for HTPs, the draw resistance can impact the ease of drawing air into the product to produce aerosol, which can affect smoke constituent yields.
- For ENDS, puff count can affect total toxicants emissions (Ref. 61). Similarly for HTPs, the puff count can affect puff volume, which in turn can affect total toxicant emissions.
- For ENDS, e-liquid capacity of the atomizer tank / cartridge can affect total toxicant emissions (Refs. 61 and 62). Similarly for HTPs, the product volume (capacity of the cartridge) can affect total puff volume, which, in turn, can affect total toxicant emissions.
- For ENDS, airflow rate can impact aerosol exposure (Ref. 54). Similarly for HTPs, the airflow rate allows air to flow from the heating element to the user's mouth; some

products allow the user to manually change the airflow while others have a minimum airflow that activates the product. Overall, airflow rate will impact aerosol exposure.

- For cigars, ventilation may affect smoke constituents yields (Ref. 34). Similarly for HTPs, ventilation may affect smoke constituent yields.
- For ENDS, the battery and PDU voltage can impact volatile aldehydes emission (Ref. 65). Similarly for HTPs, the battery and PDU voltage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes.
- For ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs the temperature sensor is a safety feature that allows the product power to be cut off to ensure the product does not get too hot, causing the battery to vent or harm the user.
- For cigarettes, the paper length and width may affect puff count and smoke constituents (Ref. 36). Similarly for HTPs, the material wrapper length and width may directly influence the area through which the air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields.
- For cigarettes, the cigarette paper basis weight may affect puff count and smoke constituents (Ref. 36). Similarly for HTPs, the material wrapper basis weight may affect puff count and smoke constituent yields.
- For cigars, the cigar wrapper porosity may affect smoke constituent yields (Refs. 37 and 38). Similarly for HTPs, the material porosity may affect smoke constituent yields.
- For ENDS, the heating element configuration and the temperature it reaches based on the type of heating element and its configuration, can affect the chemical and physical characteristics of the aerosol delivered to the user (Refs. 56-59). Similarly, for HTPs,

different heating element sources, such as coils, can reach different temperatures, which affects the chemical and physical characteristics of the aerosol delivered to the user.

- For ENDS, the temperature of the heating element can affect the chemical and physical characteristics of the aerosol delivered to the user (Refs. 56-59). Similarly for HTPs, the temperature of the heating element (heating element temperature range, operational temperature, maximum temperature) can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in heating element temperature can increase HPHC levels in the aerosol; therefore, maximum heating element temperature and temperature control deviation from this maximum heating element temperature can affect toxicant emissions and nicotine delivery.
- For ENDS, the heating element temperature may affect toxicant emissions and nicotine delivery (Ref. 59). Similarly for HTPs, the heating element can have a direct effect on the heat transfer to the e-liquid or tobacco, and in turn, affect the smoke constituent yields.
- For ENDS, the heating element configuration may affect toxicant emissions and nicotine delivery (Refs. 55-59). Similarly for HTPs, the heating element configuration may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery.
- For ENDS, the heating element dimensions may affect toxicant emissions and nicotine delivery (Refs. 55-59). Similarly for HTPs, the heating element dimensions, such as length, influence the overall surface area, which affects heating element resistance, which influences the heating element temperature.
- For ENDS, the heating element mass may affect toxicant emissions and nicotine delivery (Refs. 55-59). Similarly for HTPs, the heating element mass influences the

power delivery of the battery, and in turn, the heat applied to the e-liquid or tobacco, which affects the smoke constituent yields and in turn, affects the smoke constituent yields.

- For ENDS, the heating element location may affect toxicant emissions and nicotine delivery (Refs. 55-59). Similarly for HTPs, the heating element location can affect nicotine emissions.
- For ENDS, the number of heating elements may influence the heating element temperature thereby affecting toxicant exposure and nicotine delivery (Ref. 60). Similarly for HTPs, the number of coils/heating elements present can affect overall resistance and distribution of heat dissipation.
- For ENDS, the heating element diameter or gauge may affect toxicant emissions and nicotine delivery (Refs. 55-59). Similarly for HTPs, the larger the diameter of the heating element, the lower its resistance, and vice versa. Heating element resistance may influence heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery.
- For ENDS, the heating element resistance may affect toxicant emissions and nicotine delivery (Refs. 55-59). Similarly for HTPs, the heating element resistance may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery.
- For cigars, tobacco filler mass may affect smoke constituent yields (Ref. 34). Similarly for HTPs, the tobacco filler mass may affect smoke constituent yields.
- For cigarettes, tobacco rod density may modify burn properties and smoke constituent yields (Refs. 39 and 40). Similarly for HTPs, the tobacco rod density may modify burn properties and smoke constituent yields.
- For cigarettes, the tobacco moisture or oven volatiles may affect puff count (Ref. 41). Similarly for HTPs, tobacco moisture or oven volatiles may affect puff count.

- For cigarettes, tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 42). Similarly for HTPs, tobacco filler manufacturing and processing as well as tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter.
- For e-liquids, the e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 61 and 62). Similarly for HTPs, the e-liquid volume can affect the delivery of nicotine and other toxicants to the user.
- For e-liquids, the e-liquid viscosity can affect the electronic cigarette nicotine and other toxicant delivery to the user (Refs. 60, 61, and 70). Similarly for HTPs, the e-liquid viscosity and boiling point impact the proportion of nicotine that is aerosolized (Ref. 70). The e-liquid viscosity can affect the nicotine and other toxicant delivery to the user.
- For ENDS, an increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 58). Similarly for HTPs the battery capacity is a measure of the charge stored by the battery. The higher the mAh rating, the higher the capacity of the battery and the longer it will last between charges. The longer the battery lasts, the more the user can inhale smoke constituents.
- For ENDS the battery and PDU voltage operating range and wattage effects volatile aldehydes emission (Ref. 65). Similarly for HTPs, the battery and PDU voltage operating range or wattage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63).

Similarly for HTPs the battery current range gives an indication of the safe zone for the battery to charge and what is considered its normal operating region; if the battery levels go beyond the safe zone while charging, the battery could be damaged, which could cause harm to the user.

- For ENDS, the battery and PDU voltage impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 65) Similarly for HTPs, the battery voltage indicates how much current the battery can send out to the heating element. For the same resistance, a higher voltage will send more current (and more watts) to the heating element and it will produce more vapor. There is a link between voltage and capacity because vaping at a higher wattage will produce a higher current and that will reduce the amount of time you can vape between charges. In addition, the voltage will influence the vapor temperature, and in, turn smoke yields.
- For ENDS, an increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions may lead to greater exposure to toxicant emissions (Ref. 58). Similarly for HTPs, the battery capacity rating is a measure of the average amount of current the battery releases over time under normal use. Current may influence the heating element temperature, which in turn affects toxicant emissions and nicotine delivery. In addition, battery mAh rating provides an understanding of how long a battery will last and thus the product stability.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the battery charging temperature limits give insight on the safe

range for battery charging temperatures and testing will show if the software of the battery can keep the battery in the safe zone.

- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the battery discharge temperature limits give insight on the safe range for battery discharging temperatures and testing will show if the software of the battery can keep the battery in the safe zone.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU and battery current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the end of discharge voltage is the level to which the battery voltage or cell voltage can fall before affecting the load. This helps to establish the life cycle of the battery.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU and battery current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the maximum current at which the battery can be charged continuously is usually defined by the battery manufacturer in order to prevent excessive charge rates that would damage the battery or reduce its capacity. Damage to batteries is a hazard to users.
- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU and battery current operating

range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the maximum current at which the battery can be discharged continuously is usually defined by the battery manufacturer in order to prevent excessive discharge rates that would damage the battery or reduce its capacity. Damage to batteries is a hazard to users.

- For ENDS, the battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the battery upper limit charging voltage is important to limit the maximum battery voltage during charging to prevent damage to the battery, which is a hazard to users.
- For ENDS, the battery and PDU voltage range may influence volatile aldehydes emissions (Ref. 65). Similarly for HTPs, the battery and PDU voltage impact the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes.
- For ENDS, the Battery and PDU current operating range and wattage range may influence the toxicant emissions (Refs. 57 and 59). Similarly for HTPs, the PDU current operating range and wattage operating range may influence the heating element temperature thereby affecting toxicant emissions.
- For ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the PDU temperature cutoff is an electrical safety product that interrupts electric current when heated to a specific temperature to protect the user.

- For ENDS, the battery type, failure safety features, and battery conformance to standards are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 55 and 63). Similarly for HTPs, the current cutoff is an electrical cutoff, which is an electrical safety product that interrupts electric current when a specific condition is met (temperature, current, etc.) to protect the user.
- For ENDS, the battery and PDU current operating range may influence the toxicant emissions (Refs. 57 and 59). Similarly for HTPs, the batteries should have a normal operating current range so as to not overheat the product and cause it to become a hazard to the user. In addition, this current range has a direct impact on the heating element, which in turn affects the smoke constituent yields.
- Inhaled aerosol temperatures can be damaging or uncomfortable to users who inhale aerosol above a certain temperature (Ref. 67).
- For e-liquids, aerosol parameters such as particle number concentration, count median diameter, and PM2.5 are used to characterize the amount and size of particles to which the user is exposed (Refs. 68 and 69). Similarly for HTPs, the aerosol parameters such as particle number concentration, count median diameter, and PM2.5 are used to characterize the amount and size of particles to which the user is exposed. Clinical studies have shown that exposure to large amounts of small particles can impair lung function and is correlated with cardiovascular disease.
- For cigarettes, filter pressure drop may affect smoke constituent yields (Ref. 46). Similarly for HTPs, the filter pressure drop may affect smoke constituent yields.
- For cigarettes, filter diameter, denier per filament, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 33). Similarly for the HTPs, the filter diameter, denier per filament, total denier, filter

density, and filter length may affect filter efficiency and, in turn, smoke constituent yields.

(Comment 61). Some comments provide information in response to the proposed rule's request for comment on the appropriate design parameters for cigars and pipe tobacco. These comments suggest the following list as appropriate design parameters to be addressed for cigars: cigar length; ring gauge; total tobacco mass (including wrapper mass, binder mass, and filler mass); and filter ventilation (if applicable). One comment provided this list of appropriate design parameters for pipe tobacco: tobacco filler mass (mg); tobacco cut size (mm); and tobacco moisture (%). One comment suggests that without design parameters or testing information related to cigar, hookah, pipe tobacco and other comments, the rule is deficient and further states that the final rule must include content requirements for each product category and subcategory.

(Response 61) As discussed earlier in this section, following consideration of these comments, FDA has added design parameters for cigars, pipes, waterpipes, and other tobacco products to this section. Note that FDA does not consider a tobacco product to be "new" if there are variations that fall within the product's specifications. So long as the product is manufactured within specified parameters, FDA would not consider variations within these parameters to be a design change that would result in a new tobacco product. It is also important to note that at this time, FDA does not intend to enforce the premarket requirements of sections 910 and 905(j) for tobacco blending changes required to address the natural variation of tobacco (e.g., blending changes due to variation in growing conditions) in order to maintain a consistent product. FDA agrees with the commenter's suggested list of appropriate design parameters for pipe tobacco.

- *Comparison of heating sources (§ 1107.19(b))*

In the following paragraphs, we describe the comments and our responses on § 1107.19(b). We are finalizing this subsection without change.

(Comment 62) One comment states that the information required by proposed § 1107.19(b), which states that the SE Report must include a description of the heating source for

the new and predicate tobacco products and identify any differences, or the report must state that there is no heating source in the product, is similar to the previously submitted ingredient listing information. The comment asserts that requiring manufacturers to submit this information a second time is unnecessary and would lengthen FDA's review of the SE Report.

(Response 62) Section 910(a)(3)(B) of the FD&C Act specifically identifies the heating source as one of the characteristics of a tobacco product that FDA must consider in determining whether a new tobacco product is substantially equivalent to a predicate tobacco product. We disagree that information describing the heat source of the products being compared in an SE Report is similar to or duplicative of previously submitted ingredient listing information. Although there will likely be some overlap, the ingredient listing requirement under section 904 of the FD&C Act (21 U.S.C. 387d) is a separate requirement from the requirement to submit ingredient information in a premarket application. It is necessary to receive ingredient information in an SE Report because a finding of substantial equivalence is based on a side-by-side listing of quantitative and qualitative comparisons of all product characteristics that differ between a new and predicate tobacco product.

- *Comparison of product composition (§ 1107.19(c))*

In the following paragraphs, we describe the comments and our responses on § 1107.19(c). As discussed in the introductory paragraphs to § 1107.19, we are finalizing this subsection with minor clarifying changes.

(Comment 63) Two comments took issue with the requirement in § 1107.19(c) that information on "[t]he type of tobacco, including grade and variety" be submitted in an SE Report. These comments assert that the Department of Agriculture grading system would not be useful because they claim that it is not uniformly used by farmers and manufacturers. Instead, they noted that each farmer and manufacturer has its own unique grading system and that a written record may not exist for such system.

(Response 63) FDA has decided to remove the requirement in § 1107.19(c) that applicants provide information regarding the grade and variety of tobacco type in their SE Reports. FDA agrees with the comments that tobacco grading is not uniform throughout the industry, which reduces the utility of this information in application review. In addition, FDA does not need to characterize the tobacco type to the level of detail of tobacco variety for the purposes of an SE evaluation. Instead, information regarding the tobacco curing process is more useful to FDA to characterize and analyze the tobacco used in the tobacco products and tobacco products in general. FDA is still requiring that the tobacco type (e.g., Bright, Burley, Oriental) and curing process (e.g., fire-cured, flue-cured, air-cured) be provided in SE Reports. As described in the proposed rule, the tobacco type impacts the characteristics of the products as different types have different smoke constituent profiles, including potentially different HPHC profiles (Refs. 71 and 72). The curing process also can impact HPHC profiles (Ref. 73).

- *Comparison of other features (§ 1107.19(d))*

In the following paragraphs, we describe the comments and our responses § 1107.19(d). We are finalizing this subsection with the minor clarifying changes as described in the introductory paragraphs to § 1107.19.

(Comment 64) Section 1107.19(d) lists the other features that must be included in an SE Report. One such other feature listed in § 1107.19(d) are HPHCs. Several comments express concern with the proposed requirement that data from two smoking regimens be submitted for combusted tobacco products. They state that this requirement would lead to an unnecessary and significant increase in testing burden with no corresponding benefit. However, one comment contends that, if constituent yields were reported from a single smoking regimen only, FDA would have limited and potentially misleading information about constituent yields produced by a given product.

(Response 64) We disagree that mainstream smoke data from two smoking regimens (non-intense and intense) should not be required. Each of these regimens provides unique

information on the HPHCs generated by the tobacco product under different pyrolysis conditions (i.e., varying amounts of oxygen due to smoker use). Studies have shown identical tobacco products smoked using a non-intense smoking regimen differ in the formation of volatile organic compounds (VOCs) and aldehydes than when smoked using an intense smoking regimen. A non-intense smoking regimen can provide the upper range of aldehydes generated from smoking while an intense smoking regimen can provide the upper range of VOCs generated from smoking. Exposure to VOCs and aldehydes results in an increased risk of cancer and respiratory disease, and for some of these VOCs and aldehydes tobacco smoke is the primary source of non-occupational exposure in the U.S. population (Ref. 74). Aldehydes, such as formaldehyde, have been classified as class 1 carcinogens by the International Agency for Research on Cancer. A 2018 study (Ref. 75) shows aldehyde (formaldehyde, acrolein, acetaldehyde, and crotonaldehyde) formation may increase nonlinearly, up to six times more in a non-intense smoking regimen than in an intense smoking regimen. Another study showed there is a disproportionate increase in monoaromatic VOCs under a smoking regimen where the filter ventilation is blocked (i.e., intense smoking regimen) compared to a non-intense smoking regimen (Ref. 76). Thus, the current state of science indicates: (1) there is a nonlinear correlation between the smoke data obtained by a non-intense compared to an intense smoking regimen and (2) due to variations in the oxygen environment during pyrolysis, different VOCs and aldehydes are formed in a non-intense smoking regimen than those formed in an intense smoking regimen.

Finally, considering smoke data from only one smoking regimen would result in an incomplete assessment of smoker exposure. A non-intense and intense smoking regimen provides an upper and lower range of HPHCs that are generated during the use of a combusted tobacco product; consequently, it is necessary that FDA evaluate smoke data obtained by both intense and non-intense smoking regimens.

(Comment 65) Several comments expressed concern regarding the requirement in proposed § 1107.19(d) that HPHC data be submitted, particularly as it relates to cigars, given the variety of cigars and the variability of several smoke HPHCs in filler HPHC data, the lack of smoke testing methodologies, for example, for pipes and cigars, costs of HPHC testing, and insufficient laboratory capacity. One comment also notes that FDA has not clarified which HPHCs will be required to be reported for any cigars. A few comments also maintain that FDA has not provided substantial evidence that the testing will yield meaningful results. In addition, one comment claims that FDA should not require that HPHC testing be included in an SE Report because the FD&C Act does not require it be included. One comment encourages FDA to ensure that analytical methods are appropriately validated.

(Response 65) We disagree that HPHC data should not be required in an SE Report. In determining whether a new tobacco product is substantially equivalent, it is important for FDA to understand what is placed into the product (e.g., ingredients), as well as what comes out of the product and what is, or potentially is, inhaled, ingested, or absorbed in the body (e.g., HPHCs). HPHCs are of particular importance, as they may be carcinogens and/or respiratory, cardiovascular, and/or reproductive or developmental toxicants.

With respect to the comments on the lack of smoke testing methodologies, we note that there are some cigar smoking methods that are applicable to many commercially available products, including larger cigars.[19] The cost of testing will be dependent upon a variety of factors related to the new tobacco product, including the product characteristics and proposed modifications (e.g., minor changes to ingredients may need no or limited testing information while more significant changes to tobacco blend or ingredient changes in higher quantities may require a higher number of HPHCs tested or more voluminous data). In general, the cost of

[19] See, e.g., the following CORESTA standards: CORESTA Reference Method (CRM) 65: Determination of Total and Nicotine-Free Dry Particulate Matter using a Routine Analytical Cigar-Smoking Machine – Determination of Total Particulate Matter and Preparation for Water and Nicotine Measurements; CRM 66: Determination of Nicotine in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 67: Determination of Water in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 68: Determination of Carbon Monoxide in the Mainstream Smoke of Cigars by Non-Dispersive Infrared Analysis.

testing information necessary to submit with an SE Report to determine substantial equivalence is not disproportionate for any product category. FDA acknowledges that applicants may rely on third party laboratories, the SE program has been in existence for many years, and FDA has received thousands of SE Reports, including SE reports containing information obtained from third party laboratories. Additionally, we anticipate laboratory capability and capacity will continue to expand over time to meet the needs of future applicants.

- *Shelf life and stability information (§ 1107.19(f))*

In the following paragraphs, we describe the comments and our responses on § 1107.19(f) (in the proposed rule, this was proposed as § 1107.19(e), stability information). We are finalizing subsection (f) with the changes described in the introductory paragraphs to § 1107.19.

(Comment 66) Proposed § 1107.19(e) (now subsection (f)) requires the submission of stability information for smokeless tobacco products and any other tobacco product that contains fermented tobacco. Several comments dispute that stability information is a relevant testing parameter. The comments also claim that FDA cannot require stability testing without substantial evidence regarding its necessity, and that FDA has not met this requirement.

(Response 66) We disagree. TSNAs are carcinogenic compounds that are present at very low levels in freshly harvested tobacco leaves but can increase dramatically during tobacco processing and storage (Refs. 10, 19-21, 77, 78). TSNA production is critically influenced by the microbial communities associated with the tobacco. Microbial-mediated reduction of nitrate results in production of nitrite, which further reacts with alkaloids present in tobacco to produce the carcinogenic TSNAs (Refs. 17, 18, 20, 79-82). Therefore, TSNA content in the finished tobacco products is greatly affected by a variety of factors such as tobacco processing method(s) (e.g., curing, aging, sweating, fermentation, heat treatment), product composition (e.g., humectants, preservatives), container closure system, and product storage conditions (e.g., temperature, humidity), all of which could potentially alter microbial activity and, in turn, affect

the stability of the tobacco product over the shelf life. Since bacterial communities and constituents in tobacco products can potentially change over the shelf life (Refs. 17, 83, 84), information obtained through stability testing is important for FDA to consider during its review to ensure that the tobacco products are microbiologically and chemically stable during storage and do not result in an increased risk to public health as the product sits in storage as compared to the predicate tobacco product.

- *Comparison to original predicate tobacco product (§ 1107.19(h))*

In the following paragraphs, we describe the comments and our responses on § 1107.19(h) (proposed § 1107.19(g)). We are finalizing this subsection with the changes described in the introductory paragraphs to § 1107.19, including changes for consistency with the updated definition of predicate tobacco product.

We received several comments related to this proposed subsection. In the proposed rule, we explained that FDA may request that the applicant include information related to the "original" predicate tobacco product (a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007), even if the original predicate tobacco product is back several predicate tobacco products. Due to the removal of the definition of "grandfathered," we are no longer using the term grandfathered tobacco product in this section. We describe the comments and responses on this subsection in the following paragraphs.

(Comment 67) One comment states that FDA has underestimated the burden that would be imposed by the proposed requirement that a new tobacco product be compared to the original predicate tobacco product. Other comments object to the proposed requirement arguing that it could foster anti-competitive competition and create an imbalance in the industry in favor of large manufacturers that can afford to maintain a large pool of tobacco products. In addition, they assert that smaller companies will risk non-compliance given the costs associated with complying with the rule and that the cost of compliance may cause companies to raise prices on

their goods. Instead of requiring this information, the comments suggest FDA should instead rely on data the Agency currently has including data from previously submitted SE Reports. Another comment suggests that this interpretation also is inconsistent with FDA's position that only a single predicate can be used as the basis for an SE determination because the interpretation suggests that applicants that use as a predicate a tobacco product that was previously found SE "must demonstrate multiple levels of substantial equivalence and support multiple comparisons in a single application."

(Response 67) We disagree that this requirement should or even could be deleted. This is because, as explained in the proposed rule, although an applicant can support a showing of SE by comparing the new tobacco product to a predicate tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or that FDA has previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act). This statutory provision helps FDA ensure that new tobacco products using the substantial equivalence pathway and relying on predicate tobacco products previously found SE do not vary so much from the original predicate tobacco product that the new product would actually raise different questions of public health compared to the original predicate tobacco product. New products with differences that may appear only incremental when a new tobacco product is compared to a predicate tobacco product previously found SE can lead to product "creep," which could result in the new tobacco product actually having significant changes when compared to the original predicate tobacco product. Issuance of an order under section 910(a)(2)(A)(i)(I) of the FD&C Act would undermine the public health purposes of the Tobacco Control Act (section 3) by permitting significant product evolution over time that raises different questions of public health. Such products should be submitted for premarket authorization through the PMTA pathway, which requires an applicant to demonstrate that their product is

"appropriate for the protection of the public health." FDA would only request the information described in § 1107.19(h) when necessary to ensure that any order issued by the Agency complies with section 910(a)(2)(A)(i)(I) of the FD&C Act. Before requesting this information from the applicant, FDA would review other relevant SE Reports in the chain, for example, the first SE Report that received an SE order using the original predicate tobacco product as a predicate product, to make this finding. If FDA is unable to make the finding required by section 910(a)(2)(A)(i)(I) of the FD&C Act based on the information in its files, and the applicant does not provide the needed information when requested, FDA would not be able to issue an order authorizing the new tobacco product. We disagree with the comments suggesting this requirement favors large companies or would lead to anti-competitive behavior as we expect that companies, regardless of size, maintain records such as these as part of their business practices. We note that FDA expects to be able to make the finding required by section 910(a)(2)(A)(i)(I) of the FD&C Act based on the information in its files in the vast majority of circumstances, and thus only expects applicants to need to provide additional information in unusual circumstances. In response to the comment that suggests that FDA's "look-back" approach effectively implements an SE process relying on multiple predicates, we note that where FDA must compare the new product to the original predicate tobacco product in addition to the selected predicate, each of those comparisons involves an evaluation comparing a singular new product to a singular predicate.

(Comment 68) One comment states that FDA's proposed requirement means that specifications and measurements for the original predicate tobacco products be submitted, and because those data were not required at the time the original predicate tobacco product was originally manufactured, would essentially be requiring the manufacturer to retroactively adopt certain design and manufacturing requirements for products. Other comments state that applicants would have to manufacture the original predicate tobacco products in order to comply with the proposed requirements. One comment added that the requirement would decrease

clarity, efficiency, and predictability during the SE review process. Some comments state that while it is appropriate to "compare key design parameters" to determine whether a new product has the same or different characteristics as a predicate tobacco product, the FD&C Act does not give FDA the authority to retroactively impose design requirements on tobacco products, especially for provisional tobacco products that were designed, manufactured, and marketed before the Act required submission of SE Reports. Instead, the comments assert that FDA must issue a regulation under section 906(e) to impose design criteria and that such regulation must be independent of the SE framework. One comment instead proposes a framework that would require the manufacturer to provide the specifications employed in designing the new and predicate product, confirm that those specifications were met in manufacturing the product for HPHC testing, and then compare the output to determine whether there is a difference in disease risk posed.

(Response 68) We disagree that this section requires applicants to retroactively adopt or impose certain design and manufacturing requirements for original predicate tobacco products. FDA is not imposing design parameters on original predicate tobacco products and section 906(e) of the FD&C Act does not apply here. Rather, this section is intended to make applicants aware that in certain cases FDA may need to request information related to the original predicate tobacco product when necessary to ensure that any order issued by the Agency complies with section 910(a)(2)(A)(i)(I) of the FD&C Act. As explained in a preceding response, before requesting this information from the applicant, FDA would review its own files for other relevant SE Reports in the chain, for example, the first SE Report that received an SE order using the original predicate tobacco product as a predicate product to make this finding.

(Comment 69) Some comments object to the proposed requirement that, if an applicant is using as a predicate a tobacco product found SE by FDA, and not one that is considered the original predicate tobacco product, FDA may request information related to the original predicate tobacco product. The comments dispute that applicants should have to comply with

FDA's "look back" approach because under section 905(j) of the FD&C Act, an applicant may compare a new tobacco product to either a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a product previously found to be substantially equivalent. The comments also claim that the proposed requirement allowing FDA to request this information is in conflict with Congressional intent, and presents other issues, including preventing tobacco products from evolving by locking products into their 2007 composition, difficulty for applicants in obtaining data on the 2007 product, and inconsistency with FDA's proposed requirement that applicants maintain records for four years since this provision would require records in perpetuity if FDA could reach back to the 2007 product.

(Response 69) We disagree with these objections as manufacturers have been on notice since the passage of the Tobacco Control Act that FDA is required to make the comparison between the new tobacco product and the original predicate tobacco product, and, in doing so, may need to rely on previously submitted SE Reports, including those submitted by a different manufacturer. As discussed in the proposed rule, the statute permits an applicant to compare its new tobacco product to either a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or one that FDA has previously found SE (section 905(j)(1)(A)(i) of the FD&C Act). However, the statute also requires FDA to make an SE determination by comparing the new tobacco product to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (section 910(a)(2)(A)(i)(I) of the FD&C Act). Therefore, to meet its statutory obligation, FDA may need to look back to previously submitted SE Reports in the SE chain that relied on the original predicate tobacco product in order to issue an SE order. This statutory provision helps FDA ensure that new tobacco products using the substantial equivalence pathway and relying on predicate tobacco products previously found SE do not vary so much from the original predicate tobacco product that the new product would actually raise different questions of public health compared to the original predicate tobacco product. New products with differences that may

appear only incremental when a new tobacco product is compared to a predicate product previously found SE may actually have had significant changes when compared to the original predicate tobacco product. Should this be the case, such that FDA cannot issue the determination required under section 910(a)(2)(A)(i)(I), the statute also provides alternative premarket pathways.

(Comment 70) Another comment supports the proposed requirement to include the information regarding the original predicate tobacco product in the SE Report. The comment states that successive iterations of SE Reports, each referencing a predicate product that is not itself the original predicate tobacco product, would attenuate the relationship between the new tobacco product and the original predicate tobacco product, thereby introducing products that are not substantially equivalent to any product actually commercially marketed (other than for test marketing) on February 15, 2007.

(Response 70) We agree with this comment and have maintained this requirement without change from the proposed rule.

- *Other comments on comparison information*

(Comment 71) A few comments request that we provide further clarity on the comparison information required to be submitted for cigars and ENDS, and particularly more clarity with respect to required HPHC information. Some comments suggest specific cigar design parameter information that should be included, such as cigar length, circumference, wrapper mass, binder mass and filter ventilation. Another comment states that is inappropriate for FDA to require cigar manufacturers to include wrapper material as part of the product properties information to be submitted since whole leaf tobacco is the wrapper material.

(Response 71) FDA is providing additional clarity related to comparison information for deemed tobacco products in this final rule. Following our consideration of the comments and based on our experience, FDA has added information to § 1107.19 to address these concerns, including as suggested by at least one comment, cigar parameter information (cigar length,

circumference, wrapper mass, binder mass, and filter ventilation) as well as additional product parameters that vary based on cigar construction (e.g., unfiltered, hand rolled). We disagree that it is inappropriate to require information on wrapper material as part of the reported cigar product properties, as the composition of the wrapper will contribute to changes in smoke constituent delivery to the user.

With respect to HPHC information, as defined in this rule and discussed in the proposed rule, HPHCs are a subset of the chemical and chemical compounds in the tobacco product, including cigars, or its tobacco smoke or emission and, accordingly, the SE Report for a cigar must include the HPHC information necessary to provide a complete comparison between the new and predicate tobacco products. CORESTA[20] has established and published methods on how to generate cigar smoke in order to quantitatively compare HPHCs found in cigar smoke. We also recommend that applicants that wish to submit a premarket application for a new ENDS, cigar, or other tobacco product consider the final guidance entitled "Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act" (76 FR 5387, January 31, 2011; revised guidance issued August 2016, see https://www.fda.gov/media/80109/download)), which FDA intends to update in the future. Although this guidance document does not break out the information for those specific tobacco product categories, this guidance document may still provide useful information for these products; additionally, applicants may request a meeting to discuss these and other issues and, as noted in the proposed rule, FDA will make every attempt to grant requests for meetings to resolve important issues (see, e.g., the guidance entitled "Meetings with Industry and

[20] CORESTA standards that applicants might consider include CORESTA Reference Method (CRM) 46: Atmosphere for Conditioning and Testing Cigars of all Sizes and Shapes; CRM 47: Cigars--Sampling; CRM 64: Routine Analytical Cigar-Smoking Machine--Specifications, Definitions and Standard Conditions; CRM 65: Determination of Total and Nicotine-Free Dry Particulate Matter using a Routine Analytical Cigar-Smoking Machine--Determination of Total Particulate Matter and Preparation for Water and Nicotine Measurements; CRM 66: Determination of Nicotine in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 67: Determination of Water in the Mainstream Smoke of Cigars by Gas Chromatographic Analysis; CRM 68: Determination of Carbon Monoxide in the Mainstream Smoke of Cigars by Non-Dispersive Infrared Analysis.

Investigators on the Research and Development of Tobacco Products" (May 25, 2012, 77 FR 31368; revised guidance issued July 2016, see https://www.fda.gov/media/83420/download)).

4. Amendments (§ 1107.20)

We proposed in § 1107.20 to establish how and when applicants may submit amendments to an SE Report, including information on when a redacted copy of the amendment might need to be submitted. The proposed section provided that an applicant could not amend an SE Report to change the predicate tobacco product and that an applicant could not amend an SE Report after FDA closed the report under proposed § 1107.44 or the report was withdrawn under proposed § 1107.22. The proposed provision also stated that amendments would generally be reviewed in the next review cycle as described in proposed § 1107.42. Following our review of comments on this section, we are finalizing the section without change. We describe the comments on this section in the following paragraphs.

(Comment 72) One comment disagrees with the proposed requirement that an applicant could not amend an SE Report to change the predicate after the report is accepted for review. This comment states that permitting applicants to change a predicate prior to the initiation of scientific review is important for products covered by FDA's current compliance policy for deemed new tobacco products that were on the market on August 8, 2016, as withdrawal of a timely submitted SE Report would impact the marketing status of the product.

(Response 72) We disagree that applicants should be permitted to change the predicate tobacco product identified in an SE Report that FDA has accepted for review. As stated in the proposed rule, changing the predicate product changes the fundamental basis of the analysis, as the comparison between the new and predicate tobacco products is the crux of the SE determination. Unless FDA refuses to accept the SE Report (§ 1107.40), FDA intends to issue an acceptance for review letter and then begin to review the SE Report . Therefore, there is no time to change the predicate tobacco product between FDA's acceptance of an SE Report for review and FDA's initiation of the review. If an applicant determines that a predicate change is

necessary, they should withdraw the initial SE Report and resubmit it as a new SE Report with the information related to the new predicate tobacco product.

5. Withdrawal by applicant (§ 1107.22) and Change in ownership of an SE Report (§ 1107.24)

Proposed § 1107.22 would establish when and how an applicant may withdraw an SE Report. We received no comments on this proposed section, and we are finalizing the section with one substitute of "part 20" for § 20.45. Proposed § 1107.24 would establish the procedures for transferring ownership of an SE Report. We received no comments on this proposed section, and we are finalizing the section without change.

E. Comments on Subpart D--FDA Review and FDA Responses

In this subpart, FDA proposed requirements related to FDA review of an SE Report, including how FDA would communicate with an applicant, review cycles, and FDA's actions on an SE Report, including issuance of orders and rescission of orders. Following our review of the comments, we are finalizing § 1107.40 with a minor change to reflect that, after receiving an SE Report, FDA will either refuse to accept the report for review or issue an "acceptance for review" letter rather than an "acknowledgement" letter, as proposed. We revised § 1107.44(a) to add a reference to § 1105.10 (refuse to accept). We revised §§ 1107.42, 1107.44, 1107.46, and 1107.48 for consistency with the updates to the definition of predicate tobacco product. We also revised § 1107.42(c) to replace a "will" with "generally intends to" to provide the Agency with some discretion following receipt of a deficient SE Report. We also revised § 1107.50 pertaining to the opportunity for a hearing in a rescission action, and we describe those revisions in more detail in the paragraphs related to that section.

We note that in addition to the general comments we received on this subpart, in the proposed rule, FDA invited comment on two issues: the appropriate amount of time to allow applicants to respond to a deficiency letter and when extensions of time should be granted. In response, some comments discuss FDA's review process generally, and many of these comments recommend that FDA change the timeframes for review and response.

In the following paragraphs, we describe the comments we received on this proposed subpart and our responses.

1. Comments on Communications Between FDA and Applicants (§ 1107.40)

Proposed § 1107.40(a) provided for general principles regarding communications between applicants and FDA and the form of these communications, e.g., phone conversations, letters, email. Proposed § 1107.40(b) addressed the purpose of meetings and that FDA would make every attempt to grant meeting requests for important issues. Proposed § 1107.40(c) described how FDA would acknowledge an SE Report, and proposed § 1107.40(d) stated that FDA would make reasonable efforts to communicate to applicants the deficiencies found in an SE report and any additional information needed for FDA's review. This section also stated that applicants must provide additional comparison information under proposed § 1107.19 if requested by FDA. Following our review of comments to this proposed section, we are finalizing the section by replacing "acknowledgement" with "acceptance for review" in paragraph (c).

(Comment 73) Some comments state that FDA should grant meetings with industry while an SE Report is pending and when FDA requests scientific information or testing in the pending SE Report. The comments reason that meetings during the review process serve to clarify and improve the quality of information required, and improve the timelines for future actions. Another comment notes that a phone conversation could help advance the review process for a request for a determination that a product was commercially marketed in the United States as of February 15, 2007 (Pre-Existing tobacco product).

(Response 73) FDA agrees that opportunities can be helpful to clarify the information being requested, e.g., in a deficiency letter with an applicant. In addition, FDA intends to use a variety of methods to communicate with applicants depending on the circumstances and issues, including but not limited to, telephone conversations, letters, and/or emails, and, therefore, in many cases a formal meeting may not be necessary. If there are complex scientific issues that require discussion, an applicant may request a meeting to discuss these and other issues and, as

noted in the proposed rule, FDA will make every attempt to grant requests for meetings to resolve important issues. However, fundamental scientific issues should be the subject of meeting requests prior to submitting an SE Report (see, e.g., the guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products").

(Comment 74) One comment argues that FDA should communicate deficiencies in SE Reports to applicants prior to issuing an NSE order. A comment requests that FDA establish dispute resolution procedures that include a mechanism for stay of an NSE order for a provisional tobacco product, and that during this period of time, FDA should be barred from making it known that the product was found to be NSE given the potentially serious business consequences of such a disclosure.

(Response 74) We note that § 1107.42(b) provides for the use of multiple review cycles allowing FDA to communicate procedural, administrative, or scientific deficiencies found during a review, rather than issuing an NSE order. There may be cases where it is in FDA's and/or the applicant's interest to not issue deficiency letters but rather issue an NSE order, and, as customary, FDA generally intends to outline the deficiencies that are the basis for the decision. This will allow applicants to consider the deficiencies and consider the best course to address the deficiencies identified in their NSE order letter. An applicant has the option to request a meeting with FDA, if they choose, and FDA intends to make every effort to grant pre-submission meetings with applicants to discuss the scientific principles in their NSE determination and how best to prepare a subsequent premarket application. In addition, the scope of this rule is SE Reports for new, non-provisional products, which should not be on the market during FDA's review. FDA intends to comply with the requirements related to disclosure of information in 21 CFR part 20 and § 1107.60. If an applicant wishes to dispute the issuance of an NSE order, they may request supervisory review of FDA decisions under § 10.75 (21 CFR 10.75).

2. Comments on Review Cycles (§ 1107.42)

Proposed § 1107.42 addressed review cycles and explained what an initial review cycle is, as well as when additional review cycles would occur and what would happen if FDA issued a deficiency notification. Following our review of comments, we are finalizing this section with a minor change to add "(other than for test marketing)" following commercially marketed in paragraph (a).

(Comment 75) Several comments state that FDA should set clear deadlines for the review process. One comment suggests that FDA's rule should establish a 90-day review timeline noting that Congress directed that FDA review "the more rigorous PMTA applications for new and novel products" "no later than 180 days after receiving the application."

(Response 75) FDA agrees that review timeframes are important for both FDA and industry. Thus, in general, FDA intends to review SE Reports and either issue a deficiency letter or make a final determination within 90 calendar days of receipt of the SE Report or amendment as proposed in § 1107.42(a).

(Comment 76) One comment disagrees with the review cycles set out in the proposed rule (initial review, at least one scientific Advice/Information request, and one preliminary finding letter), which could mean that review could take 270 days. Some comments support the proposed review process of three review-cycles, noting it provides appropriate time and resources for industry and FDA.

(Response 76) We agree with those comments that support the three review-cycle process as providing appropriate timeframes. Although the FD&C Act does not require FDA to provide multiple review cycles, FDA has provided this framework to help applicants. This final rule provides additional predictability to this review process by establishing timeframes for both FDA's review and the applicant's response. As the proposed rule explained, FDA's intent is to complete review of an SE Report submitted under § 1107.18 within a maximum of 270 review days (i.e., three 90-day review cycles). Based on FDA's review experience, an SE Report should be resolved within three review cycles, sometimes fewer. If fewer review cycles are needed,

FDA intends to decide in a shorter time period, and we expect that this rule will result in a decrease in the average number of review cycles needed to issue an order. As the tobacco industry and we continue to gain experience with submitting and reviewing, respectively, our goal would be to complete SE reviews in shorter timeframes.

It is ultimately the applicant's responsibility to provide a complete SE Report that supports a scientific finding of substantial equivalence. If the applicant receives a deficiency letter and cannot respond within the specified timeframe, they have the option to withdraw and resubmit the SE Report with the required content.

(Comment 77) Some comments propose that FDA issue a notice of refusal to accept an SE Report for review within five business days of receipt of the report. Other comments propose that an acknowledgement or refusal to accept letter should be issued within 10 business days, and that applicants have a reasonable period of time to respond, such as 30 or 60 days, with a request that for the first five deficiencies, FDA provide 60 days to respond. The comments also assert that the time permitted to respond to a deficiency letter should be based on factors such as the size of the company submitting the SE report and the type or number of deficiencies identified by FDA. Some comments state that FDA should provide 180 days for applicants to respond to deficiency letters without regard to the type or number of deficiencies. The comments propose a similar approach to extension requests, noting that the extensions should be given on a case-by-case basis, with consideration given to the nature of the request.

(Response 77) The rule will provide predictability to the review process with timeframes for both FDA review and applicant response. As already stated, it is the applicant's responsibility to provide a complete SE Report that supports a scientific finding of substantial equivalence. With respect to issuance of a refuse to accept letter, FDA has established performance goals of 21 calendar days. This action closes the SE Report; therefore, an applicant would need to submit a new SE Report in order to obtain premarket authorization through the SE pathway. For an SE Report that is accepted for review, and for which the applicant receives a deficiency letter to

which it cannot respond within the specified timeframe, the applicant has the option to withdraw and resubmit the SE Report with the required information. With respect to deficiency timeframes being based on the size of the manufacturer or the number of deficiencies involved, FDA is committed to following a consistent and transparent process for all submitters of SE Reports. As an SE Report should be complete upon submission to the Agency, if an applicant is unable to respond to the number of deficiencies in the timeframe provided in the letter, the applicant has the option to withdraw and resubmit the SE Report with the required information. FDA will review all subsequent applications without prejudice.

3. FDA Action on an SE Report (§ 1107.44) and Issuance of an order finding a new tobacco product substantially equivalent.

Proposed § 1107.44 listed the actions FDA could take after receipt of an SE Report. We received no comments on this proposed section, and we are finalizing the section with a minor change to add "for review" and a reference to § 1105.10 (to ensure applicants are aware of that provision). Proposed § 1107.46 explained when FDA would issue an order finding a new tobacco product substantially equivalent. We received no comments on this proposed section, and we are finalizing the section without change.

4. Issuance of an Order Denying Marketing Authorization (§ 1107.48)

Proposed § 1107.48 explained when FDA would issue an order that the new tobacco product cannot be marketed. After considering the comment on this proposed section, we are finalizing the section without change. We describe the comment and our response in the following paragraphs.

(Comment 78) One comment requests that FDA include a dispute resolution mechanism for those applicants that seek to challenge an adverse decision by FDA. The comment asserts that manufacturers whose products are removed from the market while NSE orders are pending appeal are harmed when the Agency does not have a formal mechanism to challenge the decision beyond 21 CFR part 10.

(Response 78) As discussed in previous paragraphs, this rule applies to new, non-provisional SE Reports, not provisional SE Reports. In general, tobacco products that are the subject of non-provisional SE reports should not be on the market prior to FDA making an SE or NSE determination. Therefore, no products would need to be removed from the market during supervisory review of an NSE determination. Applicants who wish to dispute an NSE finding can use § 10.75.

5. Rescission of an Order and FDA Response (§ 1107.50)

Proposed § 1107.50 set out the grounds for rescinding an SE order and providing notice of the opportunity for a hearing related to the Agency's intention to rescind. We are finalizing this section with some clarifications to reflect the updated definition of predicate tobacco product, as well as additions related to when notice of an opportunity for a hearing will be offered. As described in the proposed rule, FDA will generally rescind an order only after notice of an opportunity for a hearing under 21 CFR part 16 (hereinafter a Part 16 hearing). However, also as described in the proposed rule, FDA may rescind an order prior to notice of an opportunity for a hearing if it finds that there is a reasonable probability that continued marketing of the tobacco product presents a serious risk to public health. In that case, FDA will provide the manufacturer a notice of an opportunity for a hearing as soon as possible after the rescission. In addition, FDA has revised § 1107.50(b) to add paragraphs (i)-(iii) as a means of more clearly explaining that FDA may rescind an order without notice of an opportunity for a Part 16 hearing where an entity that has, on its own initiative, identified a mistake, notified the Agency of the mistake, and agreed to a rescission of the marketing order of the tobacco product without the need for a Part 16 hearing. In this narrow circumstance, providing notice of an opportunity for a hearing is an unnecessary procedural step as the applicant has already informed the Agency that they would not request a Part 16 hearing. Other than these two circumstances, FDA will offer notice of an opportunity for a Part 16 hearing prior to rescission, as described in § 1107.50(b).

We received comments on this proposed section, and we respond to those in the following paragraphs.

(Comment 79) Some comments object to § 1107.50 of the proposed regulation which provides the grounds for rescinding an SE order. The comments state that FDA was not granted authority to rescind an SE order, in contrast to FDA's express authority to withdraw a PMTA or modified risk tobacco product order. One comment objects to FDA's reliance in the proposed rule on *Ivy Sports Med. LLC* v. *Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014) (hereinafter *Ivy Sports*) as misplaced because Congress did not confer rescission authority for SE orders. This comment notes that Congress "plainly intended to displace any [rescission] authority here" as it provided misbranding, adulteration, and recall authorities to address SE orders based on false information or unanticipated safety issues. Other comments state that if the rescission provision is maintained, FDA should include clear definitions and specific time limits.

(Response 79) We disagree with the comments that suggest FDA cannot or should not rescind SE orders when the grounds set out in § 1107.50 exist. As explained in the proposed rule, this provision is based on our authority to issue an order when we can make the findings in section 910(a)(2)(A)(i) of the FD&C Act, as well as our authority in section 701 (related to issuing regulations for the efficient enforcement of the FD&C Act). Moreover, as explained in the proposed rule, this section is also based on FDA's inherent authority to timely revisit and reconsider prior decisions, as discussed in *Ivy Sports*. Although misbranding, adulteration, and recall authorities are important authorities that can be used to address safety and other issues related to a tobacco product, § 1107.50 will work in tandem with those authorities to protect the public health. For example, under § 1107.50, FDA may rescind a substantially equivalent order if the applicant has removed the new tobacco product from the market for a safety concern. If the applicant continued to market such a product without premarket authorization, that product would then be adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act. However, without rescission of an SE order, there is no adulteration,

misbranding, or other provision in the statute to address products found SE based on false information.

As discussed in the proposed rule, FDA's initiation of rescission will occur only when the grounds described in § 1107.50 exist. We agree with comments that suggest FDA should exercise this authority in a timely and judicious way; while we are declining to set specific time limits, FDA intends to initiate a rescission action within a reasonable period of time, which will depend on the circumstances of each order. For example, we note that, in the absence of applicant malfeasance, 10 months has been held to be "comfortably within the reasonableness standard" in light of the particular facts. *Ivy Sports Medicine, LLC* v. *Sebelius*, 938 F. Supp. 2d 47, 63 (D.D.C. 2013) (upholding FDA rescission of medical device clearance), *rev'd on other grounds* 767 F. 3d 81 (D.C. Cir. 2014). In the presence of applicant malfeasance, more than six years has been held to be reasonable. *Ranbaxy Labs., Ltd.* v. *Burwell*, 82 F. Supp. 3d 159, 196 (D.D.C. 2015) (upholding FDA rescission of tentative approval of abbreviated new drug applications).

F. Comments on Subpart E--Miscellaneous Provisions and FDA Responses

1. Record Retention (§ 1107.58)

Proposed § 1107.58 described record retention requirements. The proposed provision would require that records supporting an SE order be maintained for a period of not less than 4 years from the date of an SE order. After considering comments on this proposed section, we are finalizing the section without change. We describe the comments to this section and our responses in the following paragraphs.

(Comment 80) A few comments state that by requiring manufacturers to trace their products back to the original predicate product (§ 1107.19(h)), a record retention requirement of 4 years has no effect since they would have to maintain records in "perpetuity" if the manufacturer wanted to use the original predicate tobacco product at a later date.

(Response 80) Section 1107.58 states that each applicant that receives an order under § 1107.46 authorizing the marketing of a new tobacco product must maintain all records required by this subpart and records that support the SE Report for a substantial equivalence order. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. All records must be retained for a period of not less than 4 years from the date of the order even if such product is discontinued. If an applicant believes that they will want to rely on the data in the future, they may choose to retain records longer than this time period. For example, manufacturers who elect to use a predicate that is a product that has been previously found SE may need to be able to produce records relating to the original predicate tobacco product where FDA is unable to make the finding required by section 910(a)(2)(A)(i)(I) of the FD&C Act based on the information in its files.

2. Confidentiality (§ 1107.60)

Proposed § 1107.60 described how FDA would determine the public availability of any part of an SE Report and other content related to such an SE Report under this proposed section and part 20 of this chapter. After considering comments on this proposed section, we are finalizing the section without change. We describe the comments to this section and our responses in the following paragraphs.

(Comment 81) One comment objects to the level of confidentiality afforded to SE Reports noting that this has "prevented the public from having any significant information about FDA's review of such applications or the standards FDA is applying." The comment states that to obtain information about SE Reports, Freedom of Information Act (FOIA) requests must be submitted and the Agency's responses to those FOIA requests are too slow. This comment also notes that because FDA does not disclose the existence of SE Reports the public cannot participate in the consideration of such reports. Another comment disagrees with limiting disclosure of information to only the summary review or the final cycle primary discipline reviews for SE Reports found NSE (without the need for FOIA requests). This comment urges

FDA to release reviewer notes from each cycle of review to the manufacturer (or applicant), as well as information related to the measures FDA takes to ensure consistency among reviewers.

(Response 81) We decline to make any changes to the codified provisions. Although we agree with the goals of transparency, the confidentiality provisions in this section align with the requirements of FOIA, other statutory provisions governing disclosure of pending SE Reports and the information contained in such SE Reports, and 21 CFR part 20. As FDA explained in the proposed rule, the intent to market a tobacco product that is not currently marketed is often considered confidential commercial information. Consistent with this rule, FDA will continue to make available to the public information related to tobacco product premarket review and marketing orders at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders.

3. Electronic Submissions (§ 1107.62)

Proposed § 1107.62 describes the requirement for the electronic submission of an SE Report, unless the applicant requested and FDA granted a waiver request. After considering comments on this proposed section, we are finalizing this section with one minor change that the applicant include their email address to help ensure we have complete contact information. We note that we intend to periodically issue specifications and guidance pertaining to electronic submission format and organization to provide updated information related to electronic submission, e.g., as technology evolves. We describe the comments to this section and our responses in the following paragraphs.

(Comment 82) One comment believes submitting the SE Report electronically should be optional and the applicant should be permitted to submit paper reports without requesting a waiver.

(Response 82) As stated in § 1107.62, FDA requires the SE Report and supporting information to be submitted electronically, unless the applicant requested and FDA granted a waiver request. In addition, § 1107.18 requires applicants to submit the SE Report using the

forms that FDA provides (i.e., Forms FDA 3964 and 3965) (FDA forms may be found at https://www.fda.gov/about-fda/reports-manuals-forms/forms). This approach is consistent with § 1105.10, which states that FDA generally intends to refuse to accept for review an SE Report if required forms are not included with the SE Report. Also, requiring electronic submission is consistent with the requirements for other FDA regulated products, e.g., new drug applications (NDAs) and investigational new drug applications (INDs). FDA provides tools, such as eSubmitter, to facilitate the creation of an electronic submission. This is available for voluntary use by sponsors, manufacturers, and importers to create a variety of submission types within the drug, device, radiological health, tobacco, animal drug and animal food regulated industries.

Without the mandatory information from the forms and electronic submission, the processing and review of each submission would be slower and more burdensome. The use of a form also helps avoid the submission of incomplete information, which can hinder decision-making and prolong the review process. Electronic data and electronic submission enable automation in the review process, which in turn increases data quality by eliminating human error from manual data entry.

G. Comments on Other Issues for Consideration and FDA Response

FDA requested comment on whether some modifications to tobacco products that result in a new tobacco product, beyond those eligible for an exemption from substantial equivalence, might be handled through a "categorical" approach to substantial equivalence. For example, under such an approach, FDA could establish categories of modifications, and if a modification is within a category, the applicant could then submit a streamlined SE Report that identifies the modification and demonstrates substantial equivalence. We solicited comment on concerns or benefits of this type of approach, along with information on the types of modifications or categories that might be handled in this way, or should not be handled this way.

(Comment 83) Several comments support consideration of categories of modifications that could be subject to streamlined SE reviews or excluded from review, and provided specific

examples. For example, one comment presents suggestions for categories of modifications for which no SE Report should be required, such as changes based on operation of law (e.g., change made to comply with a product standard); supplier/commodity changes, modifications to ensure tobacco product consistency (e.g., blending changes and similar changes to maintain consistency); packaging changes, including changes to CCS; product quantity changes.

(Response 83) After considering these comments, FDA has determined that further consideration is needed on whether and, if so, what, categories should be created for a "categorical" approach to substantial equivalence, particularly once FDA has gained more experience and is able to identify potential categories. We note that some of the changes included as suggestions for exclusion may not require a premarket submission, i.e., a change in supplier that does not result in a new product (there is no modification to the product as a result in the change in supplier).

(Comment 84) Some comments note that there are categories of minor changes which would not raise different questions of public health. One such comment includes several modifications that the commenter states does not raise different questions of public health. The comment notes that modifications that: (1) reduce HPHC yield; (2) change quantity; (3) change product design; (4) change from loose to portioned tobacco; (5) change the packaging or container; (6) reduce ingredients; (7) change an ingredient supplier; (8) change a manufacturing process; or (9) respond to other FDA requirements should not require SE Reports because they do not raise different questions of public health.

(Response 84) We disagree that changes that result in a modification of the tobacco product should not require premarket authorization. The FD&C Act generally requires that before a new tobacco product may be introduced into interstate commerce for commercial distribution in the United States, the new tobacco product must undergo premarket review by FDA. However, depending on the modification, an applicant could proceed through the same characteristics SE pathway (which does not require a showing that any changes do not cause the

product to raise different questions of public health) or the SE exemption pathway. In addition, as with some of the previous examples, some of the changes highlighted in this comment may not result in a new tobacco product, and therefore would not require premarket review (e.g., changes to packaging that are not part of a container closure system, a change in supplier that does not result in a modification of the tobacco product, or a change in manufacturing process that does not affect the characteristics of the tobacco product).

(Comment 85) Similarly, a comment requests FDA to remove "aesthetic" changes, supplier changes, changes performed to ensure consistency of the product, and packaging changes from those modifications that would require applicants to submit an SE submission. This comment expresses concern that the rule as proposed would require a manufacturer to submit a report on a change that it may not even know took place.

(Response 85) An application is only required if the change renders a product a new tobacco product. "Aesthetic" changes that alter the name or labeling, changes to packaging that are not part of a container closure system, or other modifications that do not impact the characteristics of a tobacco product do not require submission of an SE Report. However, any modifications that create a new tobacco product must receive authorization through the submission of an application (e.g., PMTA, SE Report, or Exemption Request). Otherwise, if the new tobacco product enters into interstate commerce for commercial distribution, it would be adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

(Comment 86) One comment opposes the creation of categories of products eligible for a streamlined substantial equivalence process stating that the FD&C Act contemplates product-by-product review. This comment refers to FDA's experience with SE reviews and notes that the majority of SE Reports do not result in SE orders and that this shows "that manufacturers, if not required to produce specific evidence in support of substantial equivalence, will make claims of substantial equivalence that cannot be supported." Other comments request further clarification

on the issue. The comments request that if FDA were to adopt a categorical approach, FDA publish the list of categorical modifications appropriate under the approach.

(Response 86) Given the wide range of suggested categories and other feedback on this topic, FDA agrees with the comments that indicate further consideration is needed on whether and, if so, what, categories should be created. FDA intends to continue to consider this issue and how we might best proceed in providing additional clarity and recommendations on the premarket approach that may work best for any "category" of change.

VI. Effective Date

As stated in the proposed rule, this final rule will become effective 30 days after the final rule publishes in the *Federal Register*. FDA responds to the comments on the effective date in the following paragraphs.

(Comment 87) More than one comment requests that FDA delay or stagger the effective date of the final regulation or the submission dates for premarket applications.

(Response 87) We decline to change the effective date for the rule, or add compliance dates at this time. We note that premarket requirements already apply to new tobacco products as described in the statute and the deeming final rule (sections 905 and 910 of the FD&C Act and 81 FR 28974, May 10, 2016, see https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf, codified at 21 CFR 1101.). This rule supports those existing requirements by, among other things, providing content and format requirements related to SE Reports for new tobacco products that will help applicants prepare SE Reports and enable FDA to make SE determinations for new tobacco products.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation

is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have determined that the compliance costs are less than 0.2 percent of revenues, we certify that the rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This analysis uses the state of the world where manufacturers routinely submit SE Reports as the baseline. This final rule will impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, keep records, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from $0.4 million to $3.4 million, with a primary estimate of $1.9 million at a 3 percent discount rate, and from $0.4 million to $2.9 million, with a primary estimate of $1.6 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from $0.05 million to $0.39 million, with a primary estimate of $0.22 million at a 3 percent discount

rate and from $0.06 million to $0.42 million, with a primary estimate of $0.23 million at a 7 percent discount rate. The costs to industry range from around $200 to around $1,400 per affected entity per year, with a primary estimate of around $800 per entity per year.

The incremental benefits of this final rule are potential time-savings to industry and cost-savings to FDA. The final rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. Certifying may save applicants time in preparing their SE Reports. We anticipate shorter review times for SE Reports as a result of this final rule. In addition, based on our experience with prior SE Reports, we believe this final rule will lead to higher quality SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which will result in cost-savings. We estimate that the present value of government cost-savings ranges from $15.1 million to $150.6 million, with a primary estimate of $50.2 million at a 3 percent discount rate, and from $12.4 million to $124 million, with a primary estimate of $41.3 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from $1.8 million to $17.7 million, with a primary estimate of $5.9 million at both 3 and 7 percent discount rates. The FDA cost-savings per report ranges from around $17,700 to around $58,800, with our best estimate at around $29,400.

The qualitative benefits of this final rule include additional clarity to industry about the requirements for the content and format of SE Reports. The final rule establishes the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this final rule will make the SE pathway more predictable.

Table **1** summarizes the benefits and costs of the final rule.

Table 1.--Summary of Benefits, Costs and Distributional Effects of Final Rule

Category		Low Estimate	Primary Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$1.8 million	$5.9 million	$17.7 million	2018	7%	10 years	Cost-savings to government

Category		Low Estimate	Primary Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
		$1.8 million	$5.9 million	$17.7 million	2018	3%	10 years	Cost-savings to government
	Annualized Quantified				2018	7%	10 years	
					2018	3%	10 years	
	Qualitative							Greater certainty for SE applicants
Costs	Annualized Monetized $millions/year	$0.06 million	$0.23 million	$0.42 million	2018	7%	10 years	
		$0.05 million	$0.22 million	$0.39 million	2018	3%	10 years	
	Annualized Quantified				2018	7%	10 years	
					2018	3%	10 years	
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year				2018	7%	10 years	
					2018	3%	10 years	
		From:			To:			
	Other Annualized Monetized $millions/year				2018	7%	10 years	
					2018	3%	10 years	
		From:			To:			
Effects	State, Local or Tribal Government: No effect Small Business: No effect Wages: No effect Growth: No effect							

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost-savings over an infinite time horizon. With a 7 percent discount rate, the estimated annualized net costs equal -$5.4 million in 2016 dollars over an infinite horizon. Based on these cost-savings this final rule is considered a deregulatory action under Executive Order 13771.

Table 2.--Executive Order 13771 Summary Table (in $ Millions 2016 dollars, over infinite time horizon)

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$2.42	$0.43	$4.46	$4.76	$0.61	$8.97
Present Value of Cost Savings	$79.2	$23.7	$237.5	$184.7	$55.4	$554.1
Present Value of Net Costs	($76.7)	($23.3)	($233.0)	($180.0)	($54.8)	($545.2)
Annualized Costs	$0.17	$0.03	$0.31	$0.14	$0.02	$0.27
Annualized Cost Savings	$5.5	$1.7	$16.6	$5.5	$1.7	$16.6
Annualized Net Costs	($5.4)	($1.6)	($16.3)	($5.4)	($1.6)	($16.4)

Note: Values in parentheses denote net negative costs (i.e., cost-savings).

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 86) and at https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.

VIII. Analysis of Environmental Impact

The Agency has determined under § 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No extraordinary circumstances exist to indicate that the specific action may significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Substantial Equivalence Reports for Tobacco Products.

Description: Tobacco Products, Substantial Equivalence Reports, Requirements for Submitting Information Needed to Determine Substantial Equivalence and Maintaining Records to Support a Substantial Equivalence Report.

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the *Federal Register* of April 2, 2019. In response to this rule FDA received the following PRA related comments:

(Comment 88) Some comments state that FDA underestimated the burden associated with collecting the information and suggest the proposed collection of information would have better utility and value if FDA went by product category. Specifically, the comments take issue with estimates of 683 SE reports filed and state that FDA failed to consider foreign manufacturers filing when the Agency used the registration and listing data to estimate the associated burden with the requirements. The comments also state that FDA has underestimated the burden of the proposed collection of information on FDA and does not reflect the level of agency resources needed to review the thousands of SE reports.

(Response 88) We disagree. The rule reflects estimates of the burden for the submission and review of SE Reports beginning when the rule becomes effective, which will be 30 days after the final rule publishes. These estimates reflect what we expect will be the level of submissions and burden at that time, based on our experience with SE Reports since the inception of the program. We disagree that we did not account for foreign firms. For SE purposes foreign firms are handled the same way as domestic firms. Although foreign firms are currently not required to register and list, they must still provide a U.S. agent to export a tobacco product.

(Comment 89) Several comments stated that our estimate of 87 to 300 hours to prepare and submit an SE Report is too low and that this must not account for the burden associated with HPHC testing. Several comments suggest that, based on the commenters' experience, it will take approximately 900-1,000 hours to prepare an SE Report for one product, and other comments estimate that it may take 15-28 months to prepare an SE Report depending on the scientific testing required. One comment asserts that this estimate is too low because the Agency is assuming a single submission, when the commenter's experience is that multiple submissions may be made with an SE Report including the original report. In addition, the comment states that this estimate does not include the time associated with amending the SE Report or an environmental assessment. The comment states that FDA may need multiple years to review and process SE Reports for tobacco products subject to the deeming final rule ("deemed tobacco

products”), such as cigars, and that FDA will likely make multiple requests to applicants for additional information. One comment states that SE Reports require extensive data that could take thousands of hours per application to prepare and submit.

(Response 89) Because the estimates are based on our experience with SE Reports, we are maintaining the estimates as proposed. The SE program was originally approved by OMB in 2010. Since then, FDA has reassessed the program burden each time the collection was up for extension and other related programmatic changes in between. Additionally, we have further analysis on our reporting and recordkeeping requirements that was provided in the preamble to the proposed rule and the proposed regulatory impact analysis. We note that the final rule provides more clarity on both design parameters for cigars, pipes, and other deemed tobacco products, and also when scientific testing may be needed. This information will assist applicants in understanding the content and format of an SE report which will accelerate the process of submitting a report.

(Comment 90) A comment states that our estimated burden of “bundled” SE Reports is significantly lower than our estimate for a single product. The comments believe that this is wrong because the bundled applications cover multiple products and should therefore be greater than the burden associated with preparing a report for a single product.

(Response 90) We agree that the total time to submit a bundled SE Report is greater than the time to submit a report for a single product. Our estimates for “bundled” SE Reports were the time associated with submitting for each additional product in the bundle. Therefore, the total cost for submitting a bundle of 3 products would be the full SE burden for the first product, plus two times the burden to submit a bundled report. We have clarified this in the final analysis.

(Comment 91) Several commenters provided estimates for the hours needed for preparing and submitting SE Reports of between 900 hours and 28 months. Based on these hours, the commenters estimate that the cost per SE Report could be between $250,000 and $2,000,000, although they state there may be some economies of scale in submitting multiple reports.

(Response 91) We believe some commenters have confused cost estimates from the regulatory impact analysis (RIA) and burden hours from the PRA. Although these concepts are similar and account for some corresponding items, they ultimately serve different purposes and separate functions. The PRA estimates burden in hours on an annual basis generally for three years; while the regulatory impact analysis uses these estimated burden hours on an annual basis, along with an estimate of wage per hour, to estimate a cost in terms of dollars over a long-term horizon. See comment 4 of the RIA and comment 1 in the appendix of the RIA for a further discussion regarding costs and see comments 2 and 3 of the RIA for discussion on burden hours.

(Comment 92) A comment states that they believe our estimated burden for an environmental assessment is too high as a proportion of the time to prepare and submit an SE Report. They state that our estimate of 52 to 80 hours for an EA is potentially more than our estimated burden for an SE Report at 35 to 220 hours. Other comments suggest that the burden associated with EAs is too low.

(Response 92) FDA has estimated 80 hours for an environmental assessment for the SE program for many years. Based on experience with SE Reports, interactions with the industry, and information related to other regulated products we do not have evidence suggesting a different estimate and note that the range given for EAs is intended to reflect the variation that might exist depending on the specific tobacco product.

(Comment 93) Several comments believe that FDA has substantially underestimated the number of SE Reports it will receive annually. The comments state that FDA should expect tens of thousands of SE Reports--much higher than the proposed rule estimate of 683 standalone SE Reports and 456 bundled SE Reports each year. Additionally, the commenter also notes that it expects to submit well over 100 reports per year as opposed to the FDA estimate of one application per year.

(Response 93) FDA believes our PRA estimates are accurate as we have had years of experience with the SE pathway. The SE program was originally approved by OMB in 2010.

Since then FDA has reassessed the program burden each time the collection was up for extension and other related programmatic changes in between. Additionally, we have further analysis that was provided in the preamble to the proposed rule and the proposed regulatory impact analysis. As referenced in the proposed rule, many of our estimates were based on submissions being bundled. As is currently the practice, applicants may continue to bundle groups of SE Reports submitted under § 1107.18 that have the same proposed modifications (e.g., a change in ingredient supplier that results in a new tobacco product). Co-packaging two or more tobacco products may result in a new tobacco product. When groups of full or product quantity change SE Reports have identical content, they may be submitted together (bundled); when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report.

Section 1107.18, paragraphs (b) and (c) include requirements that the applicant use the forms that FDA provides when submitting an SE Report. Following our consideration of the comments related to the forms, we are finalizing these requirements without change. We describe the comments to these sections and our responses next.

(Comment 94) At least one comment states that use of the FDA forms should be optional rather than mandatory.

(Response 94) We disagree. As explained in the proposed rule, the requirements in this rule, including use of these forms, are intended to provide clarity to applicants with respect to what they should submit in an SE Report and to help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially

equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007. Additionally, use of a standardized form allows FDA to receive information in a way that allows for faster processing and uploading of the SE Report and its contents, thereby increasing efficiency of the review process.

(Comment 95) Another comment notes that although FDA appears to recognize that the evidence required in an SE Report depends on whether new tobacco product has "same" characteristics as the predicate product or if the new tobacco product has "different" characteristics than the predicate product, this distinction is not reflected in either the draft of Form FDA 3965 or the rule itself.

(Response 95) We disagree. The form and the rule are structured to clarify both the common elements ("same" characteristics) and distinct elements ("different" characteristics) of SE Reports for both new tobacco products with the "same" characteristics as the predicate product and for new tobacco products with "different" characteristics than the predicate product. This includes reference to and discussion of these elements in the forms and throughout the rule. Applicants should indicate that their report is a "same characteristics" report where no data is necessary to demonstrate that the new tobacco product is substantially equivalent to its predicate. The form has been revised to include a section where the applicant would distinguish whether they are submitting a "same characteristics" SE Report, or a "different characteristics" SE Report. For a "same characteristics" SE Report, an applicant must describe the modification and certify that is the only change between the new and predicate tobacco product.

(Comment 96) One comment believes FDA has underestimated the time needed to complete the forms and did not explain how it arrived at these estimates.

(Response 96) FDA conducted a thorough analysis of the current paperwork burden associated with the SE program and other similar forms and applied the most accurate burden to the forms; however, upon consideration of this comment and certain updates made to the form based on comments received and product categorization changes FDA is revising the burden

associated with entering the data into the form (which includes searching existing data sources and gathering and maintaining the data needed) to be 45 minutes per individual product (rather than 30 minutes per product) on Form FDA 3965. For Form FDA 3964, FDA is revising the burden for this form to 10 minutes (from 5 minutes). This form serves several purposes from changing a point of contact (minimal burden) to providing additional substantive information for the purpose of the review of the SE Report (more burdensome). FDA notes that the comment did not provide a recommendation for the alternative estimates FDA might consider.

Description of Respondents: Manufacturers of tobacco products who submit SE Reports.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

This establishes requirements for the content and format of SE Reports (§§ 1107.18 and 1107.19). Most of the requirements mirror current practices and recommendations related to the submission of SE Reports, including information related to part 25 (environmental considerations), but the rule provides both applicants and FDA more certainty regarding the content and format for the SE Reports. A health information summary or statement would continue to be required (section 910(a)(4) of the FD&C Act) and the health summary or response to a request would be required to be in the format of a redacted SE Report, along with any additional health information about the new tobacco product, including any information, research, or data about adverse health effects, that the applicant has or knows about and that is not contained in the SE Report.

As is currently the practice, the rule continues to permit amendments for SE Reports submitted under § 1107.18, e.g., to address deficiencies (§ 1107.20). Also, in accordance with current practice, the rule continues to permit withdrawals (§ 1107.22) of pending SE Reports. The rule also describes requirements for when the ownership of an SE Report changes to ensure that FDA has information related to the current applicant (§ 1107.24).

The rule establishes a recordkeeping requirement, under which applicants are required to maintain records supporting the SE Report for an authorized new tobacco product for 4 years from the date of an order finding substantial equivalence, even if such product is discontinued (§ 1107.58).

The rule requires that respondents submit an SE Report in an electronic format, unless a waiver from this requirement is requested by the applicant and granted by FDA (§ 1107.62). FDA created two new forms for submission; Form FDA 3964, Tobacco Amendment and General Correspondence; and Form FDA 3965, Tobacco Substantial Equivalence Report Submission.

FDA estimates the burden as the following:

Table 3.-- Existing Burden for OMB Control Number 0910-0673, Estimated Annual Reporting Burden[1]

Activity; 21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Full SE 905(j)(1)(A)(i) and 910(a)	683	1	683	300	204,900
Full SE 905(j)(1)(A)(i) and 910(a) Bundled	456	1	456	90	41,040
Product Quantity Change SE Report	239	1	239	87	20,793
Product Quantity Change Bundled SE Report	192	1	192	62	11,904
Total					278,637278,637

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This chart represents the currently OMB approved burden for the SE program.

Table 4.--New Burden Per the Final Rule, Estimated Annual Reporting Burden[1]

Activity; FDA Form; 21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3965--Tobacco Substantial Equivalence Report Submission	1,570	1	1,570	.75 (45 minutes)	1,178
FDA 3964--Tobacco Amendment and General Correspondence	628	1	628	.16 (10 minutes)	100
Waiver from Electronic submission 1107.62 (b)	240	1	240	.25 (15 minutes)	60
Totals					1,338

Table 5.--Final Reporting Table 3 + 4 Reporting Burden, Estimated Annual Reporting Burden[1]

Activity; FDA Form; 21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
SE Report--1107.18	683	1	683	300	204,900
Bundled SE--1107.18	456	1	456	90	41,040
SE Report where applicant provides certification for identical characteristics--1107.18(g) and 1107.18(*l*)(2)	239	1	239	87	20,793
SE Report where applicant provides certification for some identical characteristics (bundled)--1107.18(g) and 1107.18(*l*)(2)	192	1	192	62	11,904
FDA 3965--Tobacco Substantial Equivalence Report Submission	1,570	1	1,570	.75 (45 minutes)	1,178
FDA 3964--Tobacco Amendment and General Correspondence Report	628	1	628	.16 (10 minutes)	100
Waiver from Electronic submission--1107.62(b)	240	1	240	.25 (15 minutes)	60
Totals					279,975

Table 6.-- New Recordkeeping Burden Per the Final Rule, Estimated Annual Recordkeeping Burden[1]

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping SE Report under 1107.18-1107.58	471	1	471	5	2,355

FDA's estimates are based on experience with SE Reports, registration and listing data, interactions with the industry, and information related to other regulated products. Utilizing registration and listing data for deemed tobacco products, the estimated annual number of SE Reports is expected to be 1,570. The expected number of reports has not changed since the proposed rule. As discussed earlier in this rule, FDA is not finalizing the proposed SE rule with respect to "premium" cigars. As such, the estimate of the number of reports expected is likely an overestimate as it includes "premium" cigars, which are excluded from the scope of this final rule.

When groups of full SE Reports or SE Reports that each contain a certification that some characteristics have identical content, they may be bundled; when a group of similar reports are

bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA expectations regarding the tobacco industry's use of the substantial equivalence pathway to market their products. Table 3 describes the annual reporting burden for compliance with the requirements to demonstrate substantial equivalence under the FD&C Act. We do not expect a large burden increase for this program, as, without the rule, manufacturers would routinely submit SE Reports for new tobacco products, and the Agency believes most respondents are currently practicing most of the requirements. FDA will revise this collection with the new burden.

Table 4 describes the annual reporting burden as a result of the requirements in §§ 1107.18 and 1107.19, implementing the substantial equivalence requirements of sections 905(j)(1)(A)(i) and 910(a) of the FD&C Act. This rule requires manufacturers to submit SE Reports electronically (§ 1107.62). We estimate that it would initially take about 45 minutes per product to fill out the Form FDA 3965. However, for amendments we estimate that filling out the Form FDA 3964 will take 10 minutes as applicants can copy and paste from the first submission. Section 1107.62(b) also allows for waivers from the electronic format requirement. FDA estimates that 240 respondents or 15 percent of SE Reports (1,570) will submit a waiver.

Based on updated information, FDA estimates that it will receive 683 full initial SE Reports for a new tobacco product each year under § 1107.18 that take a manufacturer approximately 300 hours to prepare. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report. We expect to receive 456 bundled SE Reports under § 1107.18

(other than the initial SE Report in the bundle) at approximately 90 hours per response for a total of 41,040 hours.

In the absence of more specific information concerning SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(*l*)(2), FDA estimates receiving 239 such SE Reports at 87 hours per response for a total of 20,973 hours. We also estimate receiving 192 bundled SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(*l*)(2) (other than the initial SE Report in the bundle) at 62 hours per response for a total of 11,904 hours. Although we believe that the number of SE Reports that include a certification will increase because the rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product, in the absence of specific information on how many more applicants might choose to certify, we are maintaining our previous estimates at this time.

FDA has based these estimates on the full analysis of economic impacts and experience with the recently-revised existing information collection (OMB Control Number 0910-0673) that applies to tobacco products. In addition, anyone submitting an SE Report is required to submit an environmental assessment prepared in accordance with § 25.40 under § 1107.18(k). The burden for environmental reports has been included in the burden per response for each type of SE Report.

Based on FDA's experience with EAs for currently regulated tobacco products, we expect industry to spend 80 hours preparing an environmental assessment for a full SE Report under § 1107.18.

Generally, an applicant may withdraw its SE Report after submission (§ 1107.22), change the ownership of its SE Report (§ 1107.24), and amend its SE Report (§ 1107.20). Currently, FDA has an OMB approved information collection for SE. The information required to grant

these applications is already being collected under the OMB approval, so we do not expect a change in burden to these sections.

FDA estimates that 30 percent of SE Reports or 471 respondents will maintain required records related to their SE Reports at 5 hours per record for a total of 2,355 recordkeeping hours. FDA has revised the estimated burden for recordkeeping per hour from 2.5 hours per record to 5 hours. As discussed in the RIA, the first SE Report in a chain must use a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, as a predicate product for the SE Report. Therefore, we believe that manufacturers will have records on those "original" predicate tobacco products from their initial SE Reports. Based on this assumption, this requirement could lead to manufacturers keeping records for a longer time. The final regulatory impact analysis estimates zero to 10 hours per entity each year for recordkeeping, and the PRA estimate has assumed a mid-point of that estimate.

FDA estimates that the burden for new requirements will increase this collection by 3,693 hours (1,338 reporting + 2,355 recordkeeping). The burden for the submission of substantial equivalence information is estimated to total 282,330 hours (279,975 reporting and 2,355 recordkeeping). This rule also refers to previously approved collections of information found in FDA regulations.

Section 1107.40 references meetings that may be held with applicants who want to meet with FDA to discuss scientific and other issues. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products." The collections of information in the guidance referenced have been approved under OMB control number 0910-0731. In addition to the premarket application under section 910(b) and a report under 905(j)(1)(A)(i) of the FD&C Act, certain new tobacco products may use the exemption premarket pathway (see § 1107.1). The collections of information found in § 1107.1 have been approved under OMB control number 0910-0684.

Before the effective date of this final rule, FDA will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to "construe ... a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 916(a)(2) of the FD&C Act is an express preemption provision. Section 916(a)(2) provides that "no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to…premarket review." Thus, the final rule creates requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. § 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not a "major rule," as defined by 5 U.S.C. § 804(2).

XII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct

effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required. We received one comment related to tribal consultation and we respond to this comment in the following paragraphs.

(Comment 97) A comment disagrees with the Agency's tentative determination that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The comment notes that FDA's decisions regarding substantial equivalence have had profound effects on the tribe's ability to raise revenue for government services and have required significant expenditures for compliance costs over the last 3 years.

The comment also states the tribe's representatives were unable to participate in an All Tribes' Call on the proposed rule due to late notice of the call. The tribe notes that, although FDA provided them with another opportunity for a call on the proposed rule, late notice of the All Tribes' Call may have caused other tribes to miss the opportunity for consultation and recommends a second All Tribes' Call with at least 30 days notice, or an in-person consultation with a phone-in option, prior to completing the next phase of rulemaking.

(Response 97) The impact and costs of the proposed rule on tribal manufacturers were considered as part of the Preliminary Regulatory Impact Statement. FDA agrees that collaboration and consultation with Federally recognized tribal governments, per the FDA Tribal Consultation Policy and Executive Order 13175, is important. FDA engages with tribal stakeholders, including tribal government leaders, tribal health leaders, and public health professionals, about the implementation and enforcement of the Tobacco Control Act and related regulations by various methods (e.g., "Dear Tribal Leader" letters, All Tribes' Calls, formal and

informal consultations as well as face-to-face meetings). We also encourage tribes to stay informed about developments related to tobacco products through our website (https://www.fda.gov/TobaccoProducts).

There were several opportunities for tribes to engage with FDA about the proposed rule, including the impact and costs of the proposed rule on tribal manufacturers, which was considered as part of the Preliminary Regulatory Impact Statement (https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm). In a "Dear Tribal Leader" letter dated April 4, 2019, FDA initiated consultation with federally recognized Indian tribes on the proposed rule and invited tribes to participate in an All Tribes' Call. The purpose of the call was to provide an overview of the proposed rule, answer questions, and hear tribal comments on the proposed rule. We provided contact information in the letter and during the call to help ensure that there was a mechanism to address any further questions. To help ensure accessibility to the call, we recorded the call and made that recording available on FDA's website for 30-days following the call, and we added a transcript of the call to the docket for the rulemaking. We also encouraged tribes to submit written comments on the proposed rule and supporting documents such as the Preliminary Regulatory Impact Statement. We note that no other tribe has requested additional consultation on the proposed rule.

XIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1107

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, chapter I of title 21 of the Code of Federal Regulations will be amended as follows:

PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

2. In § 16.1(b)(2) add in numerical sequence an entry for "§ 1107.50" to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1107.50, relating to rescission of an order finding a tobacco product substantially equivalent.

* * * * *

PART 1107--EXEMPTIONS AND SUBSTANTIAL EQUIVALENCE REPORTS

3. The authority citation for part 1107 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387b, 387c, 387e(j), 387i, and 387j.

4. The heading of part 1107 is revised to read as set forth above.

5. Add subparts B through E to read as follows:

Subpart B--General

Sec.

1107.10 Scope.

1107.12 Definitions.

Subpart C--Substantial Equivalence Reports

1107.16 Submission of a substantial equivalence report.

1107.18 Required content and format of an SE Report.

1107.19 Comparison information.

1107.20 Amendments.

1107.22 Withdrawal by applicant.

1107.24 Change in ownership of an SE Report.

Subpart D--FDA Review

1107.40 Communications between FDA and applicants.

1107.42 Review cycles.

1107.44 FDA action on an SE Report.

1107.46 Issuance of an order finding a new tobacco product substantially equivalent.

1107.48 Issuance of an order denying marketing authorization.

1107.50 Rescission of order.

Subpart E--Miscellaneous

1107.58 Record retention.

1107.60 Confidentiality.

1107.62 Electronic submission.

Subpart B--General

§ 1107.10 Scope.

(a) Subparts B through E of this part apply to a substantial equivalence report (or an SE Report) for a new tobacco product, other than "premium" cigars as defined in § 1107.12, that has:

(1) Characteristics different from a predicate tobacco product and for which information is submitted to demonstrate it is not appropriate to regulate the product under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health or

(2) The same characteristics as a predicate tobacco product.

(b) These subparts set forth procedures and requirements for the submission to FDA of an SE Report under sections 905 and 910 of the Federal, Food, Drug, and Cosmetic Act; the basic criteria for establishing substantial equivalence; and the general procedures FDA will follow when evaluating submissions.

§ 1107.12 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that the term does not include tobacco or a pesticide chemical residue in or on raw tobacco, or a pesticide chemical.

Applicant means any manufacturer of tobacco products who is subject to chapter IX of the Federal Food, Drug, and Cosmetic Act that submits a premarket application to receive marketing authorization for a new tobacco product.

Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

Characteristic means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

Commercial distribution means any distribution of a tobacco product, whether domestic or imported, to consumers or to any person, but does not include interplant transfers of a tobacco product between establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for personal consumption or resale. "Commercial distribution" does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption.

Commercially marketed means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Composition means the materials in a tobacco product, including ingredients, additives, and biological organisms. The term includes the manner in which the materials, for example, ingredients, additives, and biological organisms, are arranged and integrated to produce a tobacco product.

Constituent means any chemical or chemical compound in a tobacco product that is or potentially is inhaled, ingested, or absorbed into the body, any chemical or chemical compound in an emission (e.g., smoke, aerosol, droplets) from a tobacco product, that either transfers from any component or part of the tobacco product to the emission or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

Container closure system means any packaging materials that are a component or part of a tobacco product.

Design means the form and structure concerning, and the manner in which, components or parts, ingredients, software, and materials are integrated to produce a tobacco product.

Distributor means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Finished tobacco product means a tobacco product, including all components and parts, sealed in final packaging (e.g., filters or filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers.

Harmful or potentially harmful constituent (HPHC) means any chemical or chemical compound in a tobacco product or tobacco smoke or emission that:

(1) Is or potentially is inhaled, ingested, or absorbed into the body, including as an aerosol or any other emission; and

(2) Causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products.

Health information statement means a statement, made under section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, that the health information related to a new tobacco product will be made available upon request by any person.

Health information summary means a summary, submitted under section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, of any health information related to a new tobacco product.

Heating source means the source of energy used to burn or heat the tobacco product.

Ingredient means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing.

Material means an assembly of ingredients. Materials are assembled to form a tobacco product or components or parts of tobacco products.

New tobacco product means:

(1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(2) Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Other features means any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. Such other features include harmful and potentially harmful constituents and any other product characteristics that relate to the chemical, biological, and physical properties of the tobacco product.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Predicate tobacco product means a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act.

Premium cigars means a type of cigar that:

(1) Is wrapped in whole tobacco leaf;

(2) Contains a 100 percent leaf tobacco binder;

(3) Contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar);

(4) Is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling);

(5) Has no filter, nontobacco tip, or nontobacco mouthpiece;

(6) Does not have a characterizing flavor other than tobacco;

(7) Contains only tobacco, water, and vegetable gum with no other ingredients or additives; and

(8) Weighs more than 6 pounds per 1,000 units.

Submission tracking number or *STN* means the number that FDA assigns to submissions that are received from a manufacturer of tobacco products, such as SE Reports and voluntary

requests for determinations that a tobacco product was commercially marketed in the United States as of February 15, 2007.

Substantial equivalence or *substantially equivalent* means, with respect to a new tobacco product being compared to a predicate tobacco product, that FDA by order has found that the new tobacco product:

(1) Has the same characteristics as the predicate tobacco product; or

(2) Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to require premarket review under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health.

Substantial equivalence report or *SE Report* means a submission under section 905(j)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act that includes the basis for the applicant's determination that a new tobacco product is substantially equivalent to a predicate tobacco product. This term includes the initial substantial equivalence report and all subsequent amendments.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the Federal Food, Drug, and Cosmetic Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g)).

Tobacco product manufacturer means any person, including a repacker or relabeler, who:

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product, or

(2) Imports a finished tobacco product for sale or distribution in the United States.

Subpart C--Substantial Equivalence Reports

§ 1107.16 Submission of a substantial equivalence report.

An applicant may submit an SE Report intended to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product. The applicant must submit the SE Report at least 90 calendar days prior to the date the applicant intends to introduce or deliver for introduction a new tobacco product into interstate commerce for commercial distribution. The applicant cannot begin commercial distribution of the new tobacco product until FDA has provided the applicant an order stating that the Agency has determined that the new tobacco product is substantially equivalent to a predicate tobacco product, unless the new tobacco product has received authorization to be marketed through another premarket pathway.

§ 1107.18 Required content and format of an SE Report.

(a) *Overview*. The SE Report must provide information uniquely identifying the new tobacco product and the predicate tobacco product, and compare the new tobacco product to either a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA previously found to be substantially equivalent. The SE Report must provide sufficient information as described in this section to enable FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007. If FDA cites deficiencies and requests information to support a statement in the SE Report, the applicant must provide that information for review to continue, or FDA may issue an order under § 1107.48. FDA generally intends to refuse to accept an SE Report for review if it does not comply with § 1105.10 and this section. The SE Report must contain the following information:

(1) General information (as described in paragraph (c) of this section);

(2) Summary (as described in paragraph (d) of this section);

(3) New tobacco product description (as described in paragraph (e) of this section);

(4) Predicate tobacco product description (as described in paragraph (f) of this section), including a statement that the predicate tobacco product has not been removed from the market at the initiative of FDA and has not been determined by judicial order to be adulterated or misbranded, and the submission tracking number of the SE order finding the predicate product SE, or the submission tracking number of, or information to support, that the predicate tobacco product was commercially marketed (other than for test marketing) in the United States as of February 15, 2007;

(5) Comparison information (as described in paragraph (g) of this section);

(6) Comparative testing information (as described in paragraph (h) of this section);

(7) Statement of compliance with applicable tobacco product standards (as described in paragraph (i) of this section);

(8) Health information summary or statement that such information will be made available upon request (as described in paragraph (j) of this section);

(9) Compliance with part 25 of this chapter (as described in paragraph (k) of this section); and

(10) Certification statement (as described in paragraph (*l*) of this section).

(b) *Format*. The applicant must submit the SE Report using the form(s) that FDA provides. The SE Report must contain a comprehensive index and table of contents, be well-organized and legible, and be written in English. As described in § 1107.62, the applicant must submit the SE Report and all information supporting the SE Report in an electronic format that FDA can process, read, review, and archive, unless FDA has provided a waiver under § 1107.62(b).

(c) *General information*. The SE Report must include the following information, using the form FDA provides:

(1) The date the SE Report is submitted;

(2) Type of submission (e.g., the SE Report or amendment to a report);

(3) FDA STN, if previously assigned;

(4) Any other relevant FDA STN, such as a voluntary request for a determination that a tobacco product was commercially marketed in the United States as of February 15, 2007, or SE Report previously found substantially equivalent (if applicable), and cross-references to meetings with FDA regarding the new tobacco product;

(5) Applicant name, address, and contact information (including email address);

(6) Authorized representative or U.S. agent (for a foreign applicant), including the name, address, and contact information (including email address);

(7) For both the new and predicate tobacco products, the following information to uniquely identify the products:

(i) Manufacturer;

(ii) Product name, including the brand and sub brand (or other commercial name used in commercial distribution); and

(iii) Product category, product subcategory, and product properties (if the product does not have a listed product property, e.g., ventilation or characterizing flavor, the report must state "none" for that property) as provided in the following table:

Table 1 to § 1107.18 (c)(7)(iii)

Tobacco Product Category	Tobacco Product Subcategory	Product Properties
(A) Cigarettes	(*1*) Filtered	--Package type (e.g., hard pack, soft pack, clam shell) --Product quantity (e.g., 20 cigarettes, 25 cigarettes) --Length (e.g., 89.1 millimeters (mm), 100 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Ventilation (e.g., none, 10%, 25%) --Characterizing Flavor(s) (e.g., none, menthol) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*2*) Non-filtered	--Package type (e.g., hard pack, soft pack, clam shell) --Product quantity (e.g., 20 cigarettes, 25 cigarettes) --Length (e.g., 89.1 mm, 100 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Characterizing Flavor(s) (e.g., none, menthol)

		--Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*3*) Other	--Package type (e.g., hard pack, soft pack, clam shell) --Product quantity (e.g., 20 cigarettes, 25 cigarettes) --Length (e.g., 89.1 mm, 100 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Ventilation (e.g., none, 10%, 25%) --Characterizing Flavor(s) (e.g., none, menthol) --Additional properties needed to uniquely identify the tobacco product (if applicable)
(B) Roll-Your-Own Tobacco Products	(*1*) Roll-Your-Own Tobacco Filler	--Package type (e.g., bag, pouch) --Product quantity (e.g., 20.1 grams (g), 16 ounces (oz.)) --Characterizing flavor(s) (e.g., none, menthol) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*2*) Rolling Paper	--Package type (e.g., box, booklet) --Product quantity (e.g., 50 sheets, 200 papers) --Length (e.g., 79.1 mm, 100 mm, 110.2 mm) --Width (e.g., 28.1 mm, 33 mm, 45.2 mm) --Characterizing flavor(s) (e.g., none, menthol, tobacco) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*3*) Filtered Cigarette Tube	--Package type (e.g., bag, box) --Product quantity (e.g., 100 tubes, 200 tubes) --Length (e.g., 89.1 mm, 100 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Ventilation (e.g., none, 10%, 25%) --Characterizing flavor(s) (e.g., none, menthol, tobacco) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*4*) Non-Filtered Cigarette Tube	--Package type (e.g., bag, box) --Product quantity (e.g., 100 tubes, 200 tubes) --Length (e.g., 89.1 mm, 100 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Characterizing flavor(s) (e.g., none, menthol, tobacco) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*5*) Filter	--Package type (e.g., bag, box) --Product quantity (e.g., 100 filters, 200 filters) --Length (e.g., 8 mm, 12.1 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Characterizing flavor(s) (e.g., none, menthol, tobacco) --Additional properties needed to uniquely identify the tobacco product (if applicable)

	(*6*) Paper Tip	--Package type (e.g., bag, box) --Product quantity (e.g., 200 tips, 275 tips) --Length (e.g., 12 mm, 15.1 mm) --Width (e.g., 27.1 mm) --Characterizing flavor(s) (e.g., none, menthol, tobacco) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*7*) Other	--Package type (e.g., bag, box, booklet) --Product quantity (e.g., 200 tips, 100 filters, 200 tubes) --Characterizing flavor(s) (e.g., none, menthol, tobacco) --Additional properties needed to uniquely identify the tobacco product
(C) Smokeless Tobacco Products	(*1*) Loose Moist Snuff	--Package type (e.g., plastic can with metal lid, plastic can with plastic lid) --Product quantity (e.g., 20 g, 2.1 oz.) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable, e.g., fine cut, long cut, straight cut)
	(*2*) Portioned Moist Snuff	--Package type (e.g., plastic can with metal lid, plastic can with plastic lid) --Product quantity (e.g., 22.5 g, 20 g) --Portion count (e.g., 15 pouches, 20 pieces) --Portion mass (e.g., 1.5 g/pouch, 1 g/piece) --Portion length (e.g., 15 mm, 20.1 mm) --Portion width (e.g., 10 mm, 15.1 mm) --Portion thickness (e.g., 5 mm, 7.1 mm) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*3*) Loose Snus	--Package type (e.g., plastic can with metal lid, plastic can with plastic lid) --Product quantity (e.g., 20 g, 2.1 oz.) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*4*) Portioned Snus	--Package type (e.g., plastic can with metal lid, plastic can with plastic lid) --Product quantity (e.g., 22.5 g, 20 g) --Portion count (e.g., 15 pouches, 20 pieces) --Portion mass (e.g., 1.5 g/pouch, 1 g/piece) --Portion length (e.g., 15 mm, 20.1 mm) --Portion width (e.g., 10 mm, 15.1 mm) --Portion thickness (e.g., 5 mm, 7.1 mm)

		--Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*5*) Loose Dry Snuff	--Package type (e.g., plastic can with metal lid, plastic can with plastic lid) --Product quantity (e.g., 20 g, 2.1 oz.) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*6*) Dissolvable	--Package type (e.g., plastic can with metal lid, plastic can with plastic lid) --Product quantity (e.g., 22.5 g, 20 g) --Portion count (e.g., 15 sticks, 20 pieces) --Portion mass (e.g., 1.5 g/strip, 1 g/piece) --Portion length (e.g., 10 mm, 15.1 mm) --Portion width (e.g., 5 mm, 8.1 mm) --Portion thickness (e.g., 3 mm, 4.1 mm) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*7*) Loose Chewing Tobacco	--Package type (e.g., bag, pouch, wrapped) --Product quantity (e.g., 20 g, 3.1 oz.) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*8*) Portioned Chewing Tobacco	--Package type (e.g., plastic can with metal lid, plastic can with plastic lid) --Product quantity (e.g., 22.5 g, 20 g) --Portion count (e.g., 10 bits) --Portion mass (e.g., 2.1 g/bit) --Portion length (e.g., 8 mm, 10.1 mm) --Portion width (e.g., 6 mm, 8.1 mm) --Portion thickness (e.g., 5.1 mm, 7 mm) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*9*) Other	--Package type (e.g., box, bag, can) --Product quantity (e.g., 20.1 g, 22.5 g, 3 oz.) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen, tobacco) --Additional properties needed to uniquely identify the tobacco product
(D) Electronic Nicotine Delivery Systems (ENDS) (Vapes)	(*1*) Open E-Liquid	--Package type (e.g., bottle, box, pod) --Product quantity (e.g., 1 bottle, 5 bottles) --E-liquid volume (e.g., 0.5 milliliters (ml)), 2 ml, 5.1 ml)

		--Nicotine concentration (e.g., 0 mg/ml), 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle) --Propylene Glycol (PG)/Vegetable Glycerin (VG) ratio (e.g., not applicable (N/A), 0/100, 50/50, 100/0) --Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*2*) Closed E-Liquid	--Package type (e.g., cartridge, pod) --Product quantity (e.g., 1 cartridge, 5 cartridges) --E-liquid volume (e.g., 0.5 ml, 2 ml, 5.1 ml) --Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle) --PG/VG ratio (e.g., N/A, 0/100, 50/50, 100/0) --Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*3*) Closed E-Cigarette	--Package type (e.g., box, none, plastic clamshell) --Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes) --Length (e.g., 100 mm, 120 mm) --Diameter (e.g., 6 mm, 8 mm) --Wattage (e.g., 100 watts (W), 200 W) --Battery capacity (e.g., 100 milliampere hours (mAh), 200 mAh) --E-liquid volume (e.g., 0.5 ml, 2 ml, 5.1 ml) --Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/e-cigarette) --PG/VG ratio (e.g., N/A, 0/100, 50/50, 100/0) --Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*4*) Open E-Cigarette	--Package type (e.g., box, none, plastic clamshell) --Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes) --Length (e.g., 100 mm, 120 mm) --Diameter (e.g., 6 mm, 8 mm) --Wattage (e.g., 100 W, 200 W) --Battery capacity (e.g., 100 mAh, 200 mAh) --E-liquid volume (e.g., 0.5 ml, 2 ml, 5.1 ml) --Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen) --Additional properties needed to uniquely identify the tobacco product (if applicable)

	(*5*) ENDS Component	--Package type (e.g., box, none, plastic clamshell) --Product quantity (e.g., 1 coil) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen, tobacco) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*6*) Other	--Package type (e.g., box, none, plastic clamshell) --Product quantity (e.g., 1 e-cigarette, 5 bottles) --Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen, tobacco) --Additional properties needed to uniquely identify the tobacco product
(E) Cigars	(*1*) Filtered, Sheet-Wrapped	--Package type (e.g., hard pack, soft pack, clam shell) --Product quantity (e.g., 20 filtered cigars, 25 filtered cigars) --Length (e.g., 89.1 mm, 100 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Ventilation (e.g., none, 0%, 10%, 25%) --Characterizing flavor (e.g., none, menthol) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*2*) Unfiltered, Sheet-Wrapped	--Package type (e.g., box, film sleeve) --Product quantity (e.g., 1 cigar, 5 cigarillos) --Length (e.g., 100.1 mm, 140 mm) --Diameter (e.g., 8 mm, 10.1 mm) --Tip (e.g., none, wood tips, plastic tips) --Characterizing flavor (e.g., none, menthol, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*3*) Unfiltered, Leaf-Wrapped	--Package type (e.g., box, film, sleeve, none) --Product quantity (e.g., 1 cigar, 5 cigars) --Length (e.g., 150.1 mm, 200 mm) --Diameter (e.g., 8 mm, 10.1 mm) --Wrapper material (e.g., burley tobacco leaf, Connecticut shade grown tobacco leaf) --Characterizing flavor (e.g., none, whiskey) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*4*) Cigar Component	--Package type (e.g., box, booklet) --Product quantity (e.g., 10 wrappers, 20 leaves) --Characterizing flavor (e.g., none, menthol, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*5*) Cigar Tobacco Filler	--Package type (e.g., bag, pouch) --Product quantity (e.g., 20 g, 16.1 oz.) --Characterizing flavor (e.g., none, tobacco, menthol, cherry)

		--Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*6*) Other	--Package type (e.g., box, booklet) --Product quantity (e.g., 1 cigar, 5 cigars, 20 leaves, 16 g) --Characterizing flavor(s) (e.g., none, menthol, cherry) --Additional properties needed to uniquely identify the tobacco product
(F) Pipe Tobacco Products	(*1*) Pipe	--Package type (e.g., box, none) --Product quantity (e.g., 1 pipe) --Length (e.g., 200 mm, 300.1 mm) --Diameter (e.g., 25.1 mm) --Characterizing flavor(s) (e.g., none, menthol, cavendish, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*2*) Pipe Tobacco Filler	--Package type (e.g., box, none) --Product quantity (e.g., 20 g, 16.1 oz.) --Tobacco cut style (e.g., standard cut, such as shag cut, bugler cut, loose cut, etc., or a pressed cut, such as flake, cube cut, roll cake, etc. or a mixture) --Characterizing flavor(s) (e.g., none, menthol, cavendish, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*3*) Pipe Component	--Package type (e.g., box, bag, none) --Product quantity (e.g., 1 bowl, 1 stem, 100 filters) --Characterizing flavor(s) (e.g., none, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*4*) Other	--Package type (e.g., box, bag, none) --Product quantity (e.g., 1 pipe, 1 bowl, 1 stem, 100 filters) --Characterizing flavor(s) (e.g., none, cherry) --Additional properties needed to uniquely identify the tobacco product
(G) Waterpipe Tobacco Products	(*1*) Waterpipe	--Package type (e.g., box, none) --Product quantity (e.g., 1 waterpipe) --Height (e.g., 200 mm, 500.1 mm) --Width (e.g., 100.1 mm, 300 mm) --Diameter (e.g., 100.1 mm, 300 mm) --No. of hoses (e.g., 1, 2, 4) --Characterizing flavor(s) (e.g., none) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*2*) Waterpipe Tobacco Filler	--Package type (e.g., bag, pouch) --Product quantity (e.g., 20 g, 16.1 oz.)

		--Characterizing flavor(s) (e.g., none, tobacco, menthol, apple) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*3*) Waterpipe Heat Source	--Package type (e.g., box, film sleeve, bag, none) --Product quantity (e.g., 150 g, 680 g) --Portion count (e.g., 20 fingers, 10 discs, 1 base) --Portion mass (e.g., 15 g/finger, 10 g/brick) --Portion length (e.g., 40 mm, 100 mm) --Portion width (e.g., 10 mm, 40 mm) --Portion thickness (e.g., 10 mm, 40 mm) --Source of energy (e.g., charcoal, battery, electrical) --Characterizing flavor(s) (e.g., none, menthol, apple) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*4*) Waterpipe Component	--Package type (e.g., box, bag, none) --Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces) --Characterizing flavor(s) (e.g., none, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*5*) Other	--Package type (e.g., box, bag, none) --Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces) --Characterizing flavor(s) (e.g., none, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)
(H) Heated Tobacco Products (HTP)	(*1*) Closed HTP	--Package type (e.g., box, none, plastic clamshell) --Product quantity (e.g., 1 device, 1 HTP) --Length (e.g., 100 mm, 120 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Wattage (e.g., 100 W, 200 W) --Battery capacity (e.g., 100 mAh, 200 mAh) --Characterizing flavor(s) (e.g., none) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*2*) Open HTP	--Package type (e.g., box, none, plastic clamshell) --Product quantity (e.g., 1 device, 1 HTP) --Length (e.g., 100 mm, 120 mm) --Diameter (e.g., 6 mm, 8.1 mm) --Wattage (e.g., 100 W, 200 W) --Battery capacity (e.g., 100 mAh, 200 mAh) --Characterizing flavor(s) (e.g., none) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*3*) HTP Consumable	--Package type (e.g., hard pack, soft pack, plastic clamshell) --Product quantity (e.g., 20 sticks, 25 cartridges) --Length (e.g., 60 mm, 82 mm)

		--Diameter (e.g., 6 mm, 8.1 mm) --Ventilation (e.g., none, 10%, 25%) --Characterizing flavor(s) (e.g., none, menthol) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*4*) HTP Component	--Package type (e.g., box, none, plastic clamshell) --Product quantity (e.g., 1 mouthpiece, 1 spacer) --Characterizing flavor(s) (e.g., none, tobacco, menthol) --Additional properties needed to uniquely identify the tobacco product (if applicable)
	(*5*) Other	--Package type (e.g., box, bag, plastic clamshell, none) --Product quantity (e.g., 1 base, 5 capsules) --Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)
Other	Other	--Package type (e.g., box, bag, plastic clamshell, none) --Product quantity (e.g., 1 base, 5 capsules) --Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry) --Additional properties needed to uniquely identify the tobacco product (if applicable)

(8) Address and the FDA Establishment Identifier number(s) of the establishments involved in the manufacture and/or importation of the new and predicate tobacco products.

(d) *Summary*. The SE Report must include a summary at the beginning of the SE Report that includes the following:

(1) A concise description of the characteristics of the new tobacco product;

(2) A statement as to whether the applicant believes the new tobacco product has the same characteristics as the predicate tobacco product or has different characteristics but any differences in characteristics do not cause the new tobacco product to raise different questions of public health; and

(3) A concise description of the similarities and differences between the new tobacco product and the predicate tobacco product with respect to their characteristics (materials, ingredients, design, composition, heating source, or other features).

(e) *New tobacco product description*. The applicant must identify one new tobacco product in the SE Report for comparison to one predicate tobacco product. The SE Report must describe the new tobacco product in sufficient detail to enable FDA to evaluate its characteristics. This part of the SE Report must include:

(1) A narrative description of the new tobacco product and detailed drawings or schematics of the new tobacco product, including its container closure system, illustrating all components or parts of the product. For a portioned tobacco product, the SE Report must also include a diagram illustrating all components or parts of the individual unit of use;

(2) A description and the function of each component or part of the new tobacco product, and an explanation of how each component or part is integrated into the design of the new tobacco product; and

(3) A concise overview of the process used to manufacture the new tobacco product. If the manufacturing process for the new tobacco product does not affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report, an applicant must state that to satisfy this provision.

(f) *Description of predicate tobacco product*. (1) The applicant must identify a predicate tobacco product that is either a tobacco product commercially marketed (other than for test marketing) as of February 15, 2007, or a tobacco product that FDA previously found to be substantially equivalent.

(2) A tobacco product to which a new tobacco product is compared must:

(i) Have been either:

(A) Commercially marketed (other than for test marketing) in the United States as of February 15, 2007, as shown by either specific information sufficient to support this in the SE Report, including a statement that "I, (insert name and position title of responsible official), confirm that the predicate tobacco product associated with this submission, (insert name of predicate tobacco product), was commercially marketed (other than for test marketing) in the

United States as of February 15, 2007," and, if applicable, reference to an STN for a previous determination by FDA that the predicate product was commercially marketed (other than for test marketing) in the United States as of February 15, 2007; or

(B) Previously determined to be substantially equivalent by FDA;

(ii) Be an individual product and not a composite of multiple products;

(iii) Not be the subject of a rescission action by FDA, as described in § 1107.50; and

(iv) Not have been removed from the market at the initiative of FDA and not have been determined by judicial order to be adulterated or misbranded.

(g) *Comparison information*. The SE Report must include a comparison of the characteristics of the new tobacco product and the predicate tobacco product. If the new tobacco product has limited changes to a characteristic(s) when compared to the predicate tobacco product, and all other characteristics are identical (e.g., a change to product quantity), the applicant must provide comparison information related to any characteristic(s) that have changed, but may certify that the other characteristics are identical under paragraph (l)(2) of this section. The applicant must maintain records supporting the certification consistent with § 1107.58.

(h) *Comparative testing information*. Other than for characteristics that are identical, and for which the applicant has certified that the characteristics are identical under paragraph (l)(2) of this section, the SE Report must provide comparative testing information that has been demonstrated to be fully validated on the characteristics of the new and predicate tobacco products except where the applicant adequately justifies that such comparative testing information is not necessary to demonstrate that the new product:

(1) Has the same characteristics as the predicate or

(2) Does not raise different questions of public health.

(i) *Statement of compliance with applicable tobacco product standards*. The SE Report must either:

(1) List and describe the action(s) taken by the applicant to comply with applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act; or

(2) State there are no applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act.

(j) *Health information summary or statement regarding availability of such information*. The SE Report must include either a health information summary or a statement that such information will be made available upon request, as provided in section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, in accordance with the following:

(1) *Health information summary*. If including a health information summary with the SE Report, the applicant must provide a copy of the full SE Report that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter; and either

(i) Provide accurate, complete, and not false or misleading, additional health information, including information, research, or data about adverse health effects, that the applicant has or knows about concerning the new tobacco product that is not contained in the SE Report; or

(ii) Provide the following statement, if true, about the new tobacco product: "Applicant does not have or know of any additional health information, including information, research or data regarding adverse health effects, about the new tobacco product that is the subject of this SE Report."

(2) *Statement regarding availability of health information*. If the applicant chooses to make the health information available upon request, the SE Report must include the following statement, with the appropriate applicant information inserted as indicated by parenthetical text, signed by an authorized representative of the applicant, made on a separate page of the SE Report, and clearly identified as "910(a)(4) health information statement": "I certify that, in my capacity as (*the position held in company by person required to submit the SE Report, preferably*

the responsible official of the applicant) of (*company name*), I will make available, upon request, the information identified in 21 CFR 1107.18(j)(3) within 30 calendar days of a request."

(3) *Content of health information*. The health information the applicant agrees to make available in paragraph (j)(2) of this section must be a copy of the full SE Report, excluding all research subject identifiers, trade secrets, and confidential commercial information, as defined in §§ 20.61 and 20.63 of this chapter; and either:

(i) Accurate, complete, and not false or misleading, additional health information, including information, research, or data about adverse health effects, that the applicant has or knows about concerning the new tobacco product and that is not contained in the SE Report; or

(ii) the following statement, if true, about the new tobacco product: "(*Company name*) does not have or know of any additional health information, including information, research or data regarding adverse health effects about the new tobacco product that is the subject of the provided SE Report."

(4) *Requests for information*. All requests for information under paragraph (j)(2) of this section must be made in writing to the authorized representative of the applicant, whose contact information will be posted on the FDA website listing substantial equivalence determinations. The applicant must provide FDA any updated information if the contact information changes.

(5) *No modified risk violations*. To the extent information is included in the health information summary or health information provided upon request under paragraphs (j)(1) and (2) of this section that is not required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act or paragraph (j) of this section, that information must not contain a statement that would cause the tobacco product to be in violation of section 911 of the Federal Food, Drug, and Cosmetic Act upon the introduction or delivery for introduction of the proposed new product into interstate commerce.

(k) *Compliance with part 25 of this chapter*. (1) The SE Report must include an environmental assessment prepared in accordance with § 25.40 of this chapter, or a valid claim

of categorical exclusion. If the applicant believes that the action qualifies for an available categorical exclusion, the applicant must state under § 25.15(a) and (d) of this chapter that the action requested qualifies for a categorical exclusion, citing the particular exclusion that is claimed, and that to the applicant's knowledge, no extraordinary circumstances exist under § 25.21.

(2) The environmental assessment must include a statement explaining whether the new tobacco product is intended to replace the predicate tobacco product after the new tobacco product receives market authorization, is intended to be a line extension of the predicate tobacco product, is intended to be introduced as an additional product by the same manufacturer, or if the new tobacco product will be introduced as an additional product but by a different manufacturer.

(l) *Certification statement*. (1) The SE Report must contain the following certification, with the appropriate information inserted (as indicated by parenthetical text), and be signed by an authorized representative of the applicant: "I (*name of responsible official*) on behalf of (*applicant*), hereby certify that (*applicant*) will maintain all records to substantiate the accuracy of this SE Report for the period of time required in 21 CFR 1107.58 and ensure that such records remain readily available to the FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties."

(2) The SE Report must include the following certification if an applicant chooses to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco products. This certification must include the appropriate information inserted (as indicated by parenthetical text) and be signed by an authorized

representative of the applicant: "I, (*name of responsible official*), on behalf of (*name of company*), certify that (*new tobacco product name*) has the following modification(s) as compared to (*name of predicate tobacco product*): (*describe modification(s), e.g., change in product quantity or change in container closure system*). Aside from these modifications, the characteristics of (new tobacco product name) and (name of predicate tobacco product) are identical. I certify that (*name of company*) understands this means there is no other modification to the materials, ingredients, design features, heating source, or any other feature. I also certify that (*name of company*) will maintain records to support the comparison information in 21 CFR 1107.19 that substantiate the accuracy of this statement for the period of time required in 21 CFR 1107.58, and ensure that such records remain readily available to FDA upon request."

§ 1107.19 Comparison information.

The SE Report must include a comparison of the characteristics of the new tobacco product to the predicate tobacco product. Where test data is submitted, the testing information must include the test protocols, quantitative acceptance criteria, and test results (including means and variances, data sets, and a summary of the results). Comparison testing must be conducted on a sufficient sample size and on test samples that reflect the finished tobacco product composition and design. The SE report must state whether the same test methods were used for the new tobacco product and the predicate product, and if the methods differed, an explanation as to how the results of the different test methods can be compared. The SE report must identify national and international standards used to test the new and predicate tobacco products and explain any deviations from the standard, or state that no standards were used for the testing. The SE report must include the following:

(a) *Comparison of product design*. The SE Report must include a description of the product designs of the new and predicate tobacco products and an identification of any differences. The SE Report must include, in a tabular format, a side-by-side comparison of each design parameter of the new and predicate tobacco products. The target specification and upper

and lower range limits must be provided for each design parameter. Test data (including test protocols, quantitative acceptance criteria, data sets (i.e., measured values), and a summary of the results) must be provided for the new and predicate tobacco products when the target specification or range limits of the new tobacco product differ from the predicate tobacco product. For tobacco cut size or particle size, when target specifications and range limits are not available, the following alternative information may be submitted in place of this information: A description of the tobacco cutting process (including a complete description of the milling, cutting, and sifting process; the control parameters of the miller or cutter; and any sift specifications) or the measured particle size distribution for the new and predicate tobacco products.

(1) *Cigarettes*. For cigarettes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 1 to § 1107.19(a)(1)

Provide Target Specification With Upper and Lower Range Limits for:
--Cigarette length (mm) --Cigarette circumference or diameter (mm) --Tobacco filler mass (mg) --Tobacco rod density (g/cm^3) --Tobacco moisture or oven volatiles (%) --Tobacco cut size (mm or cuts per inch (CPI)) --Filter ventilation (%) --Tipping paper length (mm) --Cigarette paper base paper porosity (CORESTA unit (CU)) or permeability --Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigarette paper band width (mm) --Cigarette paper band space (mm) --Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3))) --Filter length (mm) --Filter pressure drop (mm H_2O)

Table 2 to § 1107.19(a)(1)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Tobacco filler mass (mg) --Tobacco moisture (%) or oven volatiles (%)

--Filter ventilation (%) --Tobacco cut size (mm or CPI) --Cigarette paper base paper porosity (CU) --Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) --Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density (g/cm^3))) --Filter pressure drop (mm H_2O)

(2) *Smokeless Tobacco*. For portioned and non-portioned smokeless tobacco products, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 3 to § 1107.19(a)(2)

Provide Target Specification With Upper and Lower Range Limits for:
Portioned Smokeless Tobacco Products
--Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron) --Tobacco moisture (%) --Portion length (mm) --Portion width (mm) --Portion mass (mg) --Pouch material thickness (mm) (if applicable) --Pouch material porosity or permeability (CU or $L/m^2/s$) (if applicable) --Pouch material basis weight (g/m^2) (if applicable) --Nicotine dissolution rate (%/min) (if applicable)
Non-portioned Smokeless Tobacco Products
--Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron) --Tobacco moisture (%)

Table 4 to § 1107.19(a)(2)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
Portioned Smokeless Tobacco Products
--Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron) --Tobacco moisture (%) --Portion mass (mg) --Pouch material porosity or permeability (CU or $L/m^2/s$) --Pouch material basis weight (g/m^2) --Nicotine dissolution rate (%/min) (if applicable)
Non-portioned Smokeless Tobacco Products
--Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron) --Tobacco moisture (%)

(3) *Roll-your-own tobacco, rolling papers*. For roll-your-own tobacco rolling papers, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 5 to § 1107.19(a)(3)

Provide Target Specifications With Upper and Lower Range Limits for:
--Paper length (mm) --Paper width (mm) --Mass per paper (mg) --Cigarette paper base paper basis weight (g/m^2) --Cigarette paper base paper porosity or permeability (CU) --Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigarette paper band width (mm) (if applicable) --Cigarette paper band space (mm) (if applicable)

Table 6 to § 1107.19(a)(3)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Mass per paper (mg) --Cigarette paper base paper basis weight (g/m^2) --Cigarette paper base paper porosity or permeability (CU) --Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable)

(4) *Roll-your-own tobacco, non-filtered tubes*. For roll-your-own tobacco non-filtered tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 7 to § 1107.19(a)(4)

Provide Target Specifications With Upper and Lower Range Limits for:
--Tube length (mm) --Tube circumference or diameter (mm) --Tube mass (mg) --Cigarette paper base paper basis weight (g/m^2) --Cigarette paper base paper porosity (CU) --Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigarette paper band width (mm) (if applicable) --Cigarette paper band space (mm) (if applicable)

Table 8 to § 1107.19(a)(4)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Tube mass (mg) --Cigarette paper base paper basis weight (g/m^2) --Cigarette paper base paper porosity (CU) --Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s))

(5) *Roll-your-own tobacco, filtered tubes*. For roll-your-own tobacco filtered tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 9 to § 1107.19(a)(5)

Provide Target Specifications With Upper and Lower Range Limits for:
--Tube length (mm) --Tube circumference or diameter (mm) --Tube mass (mg) --Tipping paper length (mm) --Filter ventilation (%) --Cigarette paper base paper basis weight (g/m^2) --Cigarette paper base paper porosity or permeability (CU) --Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigarette paper band width (mm) (if applicable) --Cigarette paper band space (mm) (if applicable) --Filter length (mm) --Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density (g/cm^3))) --Filter pressure drop (mm H_2O)

Table 10 to § 1107.19(a)(5)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Tube mass (mg) --Filter ventilation (%) --Cigarette paper base paper basis weight (g/m^2) --Cigarette paper base paper porosity or permeability (CU) --Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density (g/cm^3))) --Filter pressure drop (mm H_2O)

(6) *Roll-your-own tobacco*. For roll-your-own tobacco, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 11 to § 1107.19(a)(6)

Provide Target Specifications With Upper and Lower Range Limits for:
--Tobacco cut size (mm or CPI) --Tobacco moisture (%) or oven volatiles (%)

Table 12 to § 1107.19(a)(6)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Tobacco cut size (mm or CPI) --Tobacco moisture (%) or oven volatiles (%)

(7) *Filtered, sheet-wrapped cigars*. For filtered, sheet-wrapped cigars, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 13 to § 1107.19(a)(7)

Provide Target Specifications With Upper and Lower Range Limits for:
--Cigar mass (mg) --Cigar wrapper basis weight (g/m^2) --Cigar binder length (mm) --Cigar binder width (mm) --Cigar binder basis weight (g/m^2) --Cigar length (mm) --Cigar overall diameter (mm) --Cigar minimum diameter (mm) (if applicable) --Cigar maximum diameter (mm) (if applicable) --Tobacco filler mass (mg) --Tobacco rod density (g/cm^3) --Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm) --Cigar wrapper porosity or permeability (CU) --Cigar wrapper length (mm) --Cigar wrapper width (mm) --Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigar wrapper band width (mm) (if applicable) --Cigar wrapper band space (mm) (if applicable) --Tipping paper length (mm) --Cigar binder porosity or permeability (CU) --Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigar binder band width (mm) (if applicable) --Cigar binder band space (mm) (if applicable) --Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density(g/cm^3))) --Filter pressure drop (mm H_2O) --Filter length (mm) --Filter diameter (mm) --Filter ventilation (%)

Table 14 to § 1107.19(a)(7)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:

--Cigar mass (mg) --Puff count --Cigar wrapper basis weight (g/m^2) --Cigar wrapper porosity or permeability (CU) --Cigar binder porosity or permeability (CU) --Cigar binder basis weight (g/m^2) --Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density (g/cm^3))) --Tobacco filler mass (mg) --Tobacco rod density (g/cm^3) --Tobacco cut size (CPI or mm) --Tobacco moisture or oven volatiles (%) --Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigar binder band width (mm) (if applicable) --Cigar binder band space (mm) (if applicable) --Cigar minimum diameter (mm) (if applicable) --Cigar maximum diameter (mm) (if applicable) --Filter ventilation (%) --Filter pressure drop (mm H_2O)

(8) *Unfiltered, sheet-wrapped cigars*. For unfiltered, sheet-wrapped cigars, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 15 to § 1107.19(a)(8)

Provide Target Specifications With Upper and Lower Range Limits for:
--Cigar length (mm) --Cigar mass (mg) --Cigar overall diameter (mm) --Cigar minimum diameter (mm) (if applicable) --Cigar maximum diameter (mm) (if applicable) --Tobacco filler mass (mg) --Tobacco rod density (g/cm^3) --Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm) --Cigar wrapper porosity or permeability (CU) --Cigar wrapper length (mm) --Cigar wrapper width (mm) --Cigar wrapper basis weight (g/m^2) --Cigar binder porosity or permeability (CU) --Cigar binder width (mm) (if applicable) --Cigar binder basis weight (g/m^2) --Cigar tip mass (mg) (if applicable) --Tip length (mm) (if applicable) --Tip inner diameter (mm) (if applicable)

--Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigar binder band width (mm) (if applicable) --Cigar binder band space (mm) (if applicable) --Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigar wrapper band width (mm) (if applicable) --Cigar wrapper band space (mm) (if applicable)

Table 16 to § 1107.19(a)(8)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Puff count --Cigar mass (mg) --Tobacco rod density (g/cm^3) --Tobacco cut size (CPI or mm) --Tobacco moisture or oven volatiles (%) --Tobacco filler mass (mg) --Cigar wrapper basis weight (g/m^2) --Cigar wrapper porosity or permeability (CU) --Cigar binder width (mm) (if applicable) --Cigar binder basis weight (g/m^2) --Cigar binder porosity or permeability (CU) --Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable) --Cigar tip mass (mg) (if applicable) --Cigar minimum diameter (mm) (if applicable) --Cigar maximum diameter (mm) (if applicable)

(9) *Unfiltered, leaf-wrapped cigars*. For unfiltered, leaf-wrapped cigars, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 17 to § 1107.19(a)(9)

Provide Target Specifications With Upper and Lower Range Limits for:
--Cigar length (mm) --Cigar mass (mg) --Overall diameter (mm) --Cigar minimum diameter (mm) (if applicable) --Cigar maximum diameter (mm) (if applicable) --Tobacco filler mass (mg) --Tobacco rod density (g/cm^3) --Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm) --Cigar wrapper length (mm) --Cigar wrapper width (mm) --Cigar wrapper basis weight (g/m^2)

--Cigar binder width (mm) --Cigar binder basis weight (g/m^2)

Table 18 to § 1107.19(a)(9)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Puff count --Cigar mass (mg) --Tobacco filler mass (mg) --Tobacco rod density (g/cm^3) --Tobacco cut size (CPI or mm) --Cigar wrapper basis weight (g/m^2) --Cigar binder basis weight (g/m^2) --Tobacco moisture or oven volatiles (%) --Cigar minimum diameter (mm) (if applicable) --Cigar maximum diameter (mm) (if applicable)

(10) *Cigar filler.* For cigar filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 19 to § 1107.19(a)(10)

Provide Target Specifications With Upper and Lower Range Limits for:
--Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm)

Table 20 to § 1107.19(a)(10)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm)

(11) *Cigar component*. For cigar components, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 21 to § 1107.19(a)(11)

Provide Target Specifications With Upper and Lower Range Limits for:
--Cigar wrapper length (mm) --Cigar wrapper width (mm) --Cigar wrapper porosity (CU) --Cigar wrapper basis weight (g/m^2)

Table 22 to § 1107.19(a)(11)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Cigar wrapper length (mm) --Cigar wrapper width (mm) --Cigar wrapper basis weight (g/m^2)

(12) *Pipes*. For pipes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 23 to § 1107.19(a)(12)

Provide Target Specifications With Upper and Lower Range Limits for:
--Bowl chamber outer diameter (mm) --Bowl chamber inner diameter (mm) --Draught hole diameter (mm) --Draught hole location --Draught hole shape --Bowl chamber hole shape --Bowl chamber volume (cm^3) --Stem length (mm) --Stem diameter (mm) --Shank length (mm) --Shank diameter (mm) --Draught hole area (mm^2) --Pressure drop through air valve (mm H_2O) --Air flow through air valve (cc/min) --Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density (g/cm^3))) --Filter pressure drop (mm H_2O) --Filter length (mm)

Table 24 to § 1107.19(a)(12)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Bowl chamber volume (cm^3) --Air flow through air valve (cc/min) --Filter length (mm) --Filter pressure drop (mm H_2O) --Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density(g/cm^3)))

(13) *Pipe filler*. For pipe filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 25 to § 1107.19(a)(13)

Provide Target Specifications With Upper and Lower Range Limits for:
--Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm)

Table 26 to § 1107.19(a)(13)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm)

(14) *Waterpipes*. For waterpipes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 27 to § 1107.19(a)(14)

Provide Target Specifications With Upper and Lower Range Limits for:
--Hose length (mm)
--Hose internal diameter (mm)
--Hose materials
--Stem length (mm)
--Stem internal diameter (mm)
--Base diameter (mm)
--Base volume (cm^3)
--Base shape
--Pressure drop (mm H_2O)
--Water filter efficiency (%)
--Hose air permeability (CU)
--Head height (mm)
--Head top diameter (mm)
--Head bottom diameter (mm)
--No. of holes
--Head volume (mm^3)
--Heating source type
--Head materials

Table 28 to § 1107.19(a)(14)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Hose length (mm)
--Hose internal diameter (mm)
--Stem length (mm)
--Stem internal diameter (mm)
--Base diameter (mm)
--Base volume (cm^3)
--Pressure drop (mm H_2O)
--Water filter efficiency (%)
--Head height (mm)
--Head top diameter (mm)
--Head bottom diameter (mm)
--Head volume (mm^3)

(15) *Waterpipe, heating source*. For waterpipe heating sources, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 29 to § 1107.19(a)(15)

Provide Target Specifications With Upper and Lower Range Limits for:
--Heating element mass (mg)
--Heating element density (g/cm^3)
--Heating element resistance (ohms) (if applicable)

--No. of heating elements --Heating element configuration --Heating element diameter (gauge) --Battery current rating (mA) (if applicable) --Battery capacity (mAh) (if applicable) --Battery voltage operating range (volts) (if applicable) --Battery current operating range (amps) (if applicable) --Power delivery unit (PDU) voltage operating range (volts) (if applicable) --PDU current operating range (amps) (if applicable) --PDU wattage operating range (watts) (if applicable) --PDU temperature cut-off (°C) (if applicable)

Table 30 to § 1107.19(a)(15)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Heating element temperature range (°C) (if applicable) --Heating element mass (mg) --Heating element density (g/cm^3) --Heating element resistance (ohms) (if applicable) --Heating element diameter (gauge) --Battery current rating (mA) (if applicable) --Battery capacity (mAh) (if applicable) --Battery voltage operating range (volts) (if applicable) --Battery current operating range (amps) (if applicable) --Power delivery unit (PDU) voltage operating range (volts) (if applicable) --PDU current operating range (amps) (if applicable) --PDU wattage operating range (watts) (if applicable) --PDU temperature cut-off (°C) (if applicable)

(16) *Waterpipe component, head*. For waterpipe heads, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 31 to § 1107.19(a)(16)

Provide Target Specifications With Upper and Lower Range Limits for:
--Head height (mm) --Head top diameter (mm) --Head bottom diameter (mm) --No. of holes --Head volume (mm^3) --Head materials

Table 32 to § 1107.19(a)(16)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Head height (mm) --Head top diameter (mm) --Head bottom diameter (mm) --Head volume (mm^3)

(17) *Waterpipe component, foil*. For waterpipe foil, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 33 to § 1107.19(a)(17)

Provide Target Specifications With Upper and Lower Range Limits for:
--Length (mm) (for square or rectangular shape foil) --Width (mm) (for square or rectangular shape foil) --Diameter (mm) (for circular shape foil) --Foil thickness (mm) --No. of holes --Diameter of the holes (mm)

Table 34 to § 1107.19(a)(17)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Length (mm) (for square or rectangular shape foil) --Width (mm) (for square or rectangular shape foil) --Diameter (mm) (for circular shape foil) --Foil thickness (mm) --Diameter of the holes (mm)

(18) *Waterpipe filler*. For waterpipe filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 35 to § 1107.19(a)(18)

Provide Target Specifications With Upper and Lower Range Limits for:
--Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm)

Table 36 to § 1107.19(a)(18)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Tobacco moisture or oven volatiles (%) --Tobacco cut size (CPI or mm)

(19) *Electronic Nicotine Delivery System (ENDS)*. For ENDS (vapes), the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 37 to § 1107.19(a)(19)

Provide Target Specifications With Upper and Lower Range Limits for:
--Draw resistance (mm H_2O) --Puff count (for full tank/cartridge) --Atomizer tank/cartridge volume (mL) --No. of heating elements (e.g., coil) --Heating element diameter (gauge) --Heating element length (mm)

--Heating element resistance (Ohms) --Heating element temperature range (°C) --Heating element configuration (target only) --Battery voltage operating range (V) --Battery current operating range (mA) --Battery capacity (mAh) --Battery nominal voltage (V) --Battery current rating (mA) --Battery charging temperature limits (°C) --Battery discharge temperature limits (°C) --Battery end of discharge voltage (V) --Battery maximum charging current (mA) --Battery maximum discharging current (mA) --Battery upper limits charging voltage (V) --Power Delivery Unit (PDU) voltage operating range (V) --PDU current operating range (mA) --PDU wattage operating range (watts) --PDU temperature cut-off (°C) (if applicable) --PDU current cut-off (mA) (if applicable) --Airflow rate (L/min) (if applicable) --Ventilation (%) --Inhaled aerosol temperature (°C)

Table 38 to § 1107.19(a)(19)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Draw resistance (mm H_2O) --Puff count (for full tank/cartridge) --Atomizer tank/cartridge volume (mL) --Heating element diameter (gauge) --Heating element resistance (Ohms) --Heating element temperature range (°C) --Battery voltage operating range (V) --Battery current operating range (mA) --PDU voltage operating range (V) --PDU current operating range (mA) --PDU wattage operating range (watts) --PDU current cut-off (mA) (if applicable) --Inhaled aerosol temperature (°C) --PDU temperature cut-off (°C) (if applicable) --Battery capacity (mAh) --Battery nominal voltage (V) --Battery current rating (mA) --Heating element length (mm) --Battery charging temperature limits (°C) --Battery discharge temperature limits (°C) --Battery maximum charging current (mA) --Battery maximum discharging current (mA) --Battery upper limits charging voltage (V) --Airflow rate (L/min) (if applicable) --Ventilation (%)

(20) *E-liquids*. For e-liquids, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 39 to § 1107.19(a)(20)

Provide Target Specifications With Upper and Lower Range Limits for:
--E-liquid viscosity (at 20°C) --E-liquid volume (ml) --Particle number concentration (#/cm^3) --Count median diameter (nm) --PM2.5 (µg/m^3)

Table 40 to § 1107.19(a)(20)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--E-liquid viscosity (at 20°C) --E-liquid volume (ml) --Particle number concentration (#/cm^3) --Count median diameter (nm) --PM2.5 (µg/m^3)

(21) *Heated Tobacco Products (HTP)*. For HTPs, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

Table 41 to § 1107.19(a)(21)

Provide Target Specifications With Upper and Lower Range Limits for:
--Overall Device - Mass (mg) - Length (mm) - Width (mm) - Height (mm) - Diameter (mm) - Draw resistance (mm H_2O) - Puff count (for full tank/cartridge) - Puff volume (mL) - Product volume (mL) - Airflow rate (L/min) (if applicable) - Ventilation (%) - Operational temperature (°C) - Temperature sensor (if applicable) - Material wrapper length (mm) (if applicable) - Material wrapper width (mm) (if applicable) - Material wrapper basis weight (g/m^2) (if applicable) - Material porosity or permeability (CU) (if applicable) --Heating element - Heating element source/type/approach (electrical, carbon, aerosol, etc.) - Heating element temperature range (°C) - Heating element operational temperature (°C)

- Heating element maximum temperature (boost temperature) (°C)
- Heating element material
- Heating element configuration
- Heating element length (mm)
- Heating element mass (mg)
- Heating element location
- No. of heating elements (e.g., coil)
- Heating element diameter (gauge) (if applicable)
- Heating element resistance (Ohms) (if applicable)

--Tobacco / E-liquid
- Tobacco mass (mg) (if applicable)
- Tobacco density (g/cm^3) (if applicable)
- Tobacco moisture or oven volatiles (%) (if applicable)
- Tobacco cut size (CPI or mm) (if applicable)
- E-liquid volume (mL) (if applicable)
- E-liquid viscosity (at 20°C) (if applicable)

--Battery (if applicable)
- Battery capacity (mAh)
- Battery voltage operating range (V) or wattage (W)
- Battery current charging range (amps)
- Battery nominal voltage (V)
- Battery current rating (mA)
- Battery charging temperature limits (°C)
- Battery discharge temperature limits (°C)
- Battery end of discharge voltage (V)
- Battery maximum charging current (mA)
- Battery maximum discharging current (mA)
- Battery upper limits charging voltage (V)
- Power Delivery Unit (PDU) voltage operating range (V)
- PDU current operating range (mA)
- PDU wattage operating range (watts)
- PDU temperature cut-off (°C) (if applicable)
- PDU current cut-off (mA) (if applicable)

--Aerosol
- Inhaled aerosol temperature (°C)
- Aerosol particle number concentration (#/cm^3)
- Count median diameter (nm)
- PM2.5 (µg/m^3)

--Filter (if applicable)
- Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density(g/cm^3)))
- Filter pressure drop (mm H_2O)
- Filter length (mm)
- Filter diameter (mm)
- Filter ventilation (%)

Table 42 to § 1107.19(a)(21)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
--Overall device - Draw resistance (mm H_2O) - Puff count (for full tank/cartridge) (dimensionless) - Product volume (mL) - Airflow rate (L/min) (if applicable) - Ventilation (%) - Operational temperature (°C) - Temperature sensor (if applicable) - Material wrapper length (mm) (if applicable) - Material wrapper width (mm) (if applicable) - Material wrapper basis weight (g/m^2) (if applicable) - Material porosity or permeability (CU) (if applicable) --Heating element - Heating element diameter (gauge) (if applicable) - Heating element resistance (Ohms) (if applicable) - Heating element temperature range (°C) --E-liquid - E-liquid viscosity (at 20°C) (if applicable) - E-liquid volume (ml) (if applicable) --Tobacco - Tobacco moisture or oven volatiles (%) (if applicable) - Tobacco cut size (CPI or mm) (if applicable) - Tobacco density (g/cm^3) (if applicable) --Battery - Battery voltage operating range (V) or wattage (W) - Battery current operating range (mA) - PDU voltage operating range (V) - PDU current operating range (mA) - PDU wattage operating range (watts) - PDU current cut-off (mA) (if applicable) - PDU temperature cut-off (°C) (if applicable) - Battery capacity (mAh) - Battery nominal voltage (V) - Battery current rating (mA) - Battery charging temperature limits (°C) - Battery discharge temperature limits (°C) - Battery maximum charging current (mA) - Battery maximum discharging current (mA) - Battery upper limits charging voltage (V) --Aerosol - Inhaled aerosol temperature (°C) - Aerosol particle number concentration ($\#/cm^3$) - Count median diameter (nm) - PM2.5 ($\mu g/m^3$)

--Filter (if applicable) - Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (e.g., DPF, total denier (g/9000m), and filter density(g/cm^3))) - Filter ventilation (%) - Filter pressure drop (mm H_2O)

(b) *Comparison of heating sources*. The SE Report must include a description of the heating source for the new and predicate tobacco products and identify any differences, or state that there is no heating source.

(c) *Comparison of product composition*. The SE Report must include descriptions of the product composition of the new and predicate tobacco products and identify any differences. The SE Report must include, in a tabular format, a side-by-side comparison of the materials and ingredients for each component or part of the new and predicate tobacco products. For each material and ingredient quantity, the target specifications and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) reported as mass per component or part, must be provided.

(1) *Materials*. For each material in the products include:

(i) The material name and common name(s), if applicable;

(ii) The component or part of the tobacco product where the material is located;

(iii) The subcomponent or subpart where the material is located, if applicable;

(iv) The function of the material;

(v) The quantities (including ranges or means, acceptance limits) of the material(s) in each new tobacco product and predicate tobacco product (with any specification variation, if applicable);

(vi) The specification(s) (including quality/grades, suppliers) used for the new tobacco product and predicate tobacco product (with any specification variations, if applicable); and

(vii) Any other material properties necessary to characterize the new and predicate tobacco products.

(2) *Ingredients other than tobacco*. For each ingredient other than tobacco in each material or component or part of the product include:

(i) The International Union of Pure and Applied Chemistry (IUPAC) chemical name and common name, if applicable;

(ii) The Chemical Abstracts Service (CAS) number(s) or FDA Unique Ingredient Identifier (UNII);

(iii) The function of the ingredient;

(iv) The quantity with the unit of measure (including ranges or means, acceptance limits) of the ingredient in the new tobacco product and predicate tobacco product reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

(v) The specification(s) (including purity or grade and supplier);

(vi) For complex purchased ingredients, each single chemical substance reported separately; and

(vii) Any other ingredient information necessary to characterize the new and predicate tobacco products.

(3) *Tobacco ingredients*. For tobacco include:

(i) The type (e.g., Bright, Burley, reconstituted);

(ii) The curing method (e.g., flue cured, dark air cured);

(iii) The quantity of each type with the unit of measure (including ranges or means, acceptance limits) of tobacco in the new tobacco product and predicate tobacco product reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products;

(iv) A description of any genetic engineering of the tobacco; and

(v) Any other information necessary to characterize the new and predicate tobacco products.

(vi) If the new tobacco product does not contain tobacco, then include a statement that the new tobacco product does not contain tobacco.

(4) *Container closure system*. A description of the container closure system for the new and predicate tobacco products, including a side-by-side quantitative comparison of the components and materials and annotated illustrations.

(d) *Comparison of other features*. The SE Report must include descriptions of any other features of the new and predicate tobacco products, such as those described in paragraphs (d)(1) and (2) of this section, and identify any differences. If a specific feature specified in paragraphs (d)(1) and (2) of this section is not applicable to the product design, this must be stated clearly. If FDA requests a scientific justification explaining why a feature is not applicable, the applicant must provide the justification to FDA. The comparison of other features must include information on:

(1) *Constituents*. HPHCs and other constituents, as appropriate, to demonstrate that:

(i) The new tobacco product has the same characteristics as the predicate tobacco product, or

(ii) Any differences in characteristics between the new and predicate product do not cause the new tobacco product to raise different questions of public health, including:

(A) The constituent names in alphabetical order;

(B) The common name(s);

(C) The Chemical Abstract Services number(s);

(D) The mean quantity and variance with unit of measure;

(E) The number of samples and measurement replicates for each sample;

(F) The analytical methods used, associated reference(s), and full validation reports for each analytical method;

(G) The testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(H) Length of time between dates of manufacture and date(s) of testing;

(I) Storage conditions of the tobacco product before it was tested;

(J) Reference product datasets (if applicable);

(K) Full test data (including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria and complete data sets) for all testing performed. Test data for combusted or inhaled tobacco products must reflect testing conducted using both intense and non-intense smoking or aerosol-generating regimens, where established; and

(L) Complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable.

(2) *Any other features*. A description and comparison of any other features of the new tobacco product and the predicate tobacco product.

(e) *Comparison of tobacco processing*. The SE Report must include information on the tobacco processes in paragraphs (e)(1) and (2) of this section for the new and predicate tobacco products, if applicable, and identify any differences.

(1) *Fermentation process*. For smokeless tobacco products and tobacco products that contain fermented tobacco (including naturally fermented tobacco), the SE Report must contain the following information regarding the fermentation process of the new and predicate tobacco products and identify any differences:

(i) Description of the fermentation process;

(ii) Composition of the inoculum (starter culture) with genus and species name(s) and concentration(s) (if applicable);

(iii) Any step(s) taken to reduce microbes already present during processing (e.g., cleaning of contact surfaces);

(iv) Specifications and test data for pH, temperature, and moisture content or water activity;

(v) Frequency of aeration or turning (if applicable);

(vi) Duration of fermentation;

(vii) Added ingredients;

(viii) Method used to stabilize or stop fermentation ((e.g., heat treatment), if applicable), including parameters of the method (e.g., length of treatment, temperature) and method validation data; and

(ix) Storage conditions of the fermented tobacco prior to further processing or packaging and duration of storage (if applicable).

(2) *Heat treatment process*. For tobacco products that are heat treated, the SE Report must contain the following information regarding the heat treatment process of the new and predicate tobacco products and identify any differences:

(i) Description of the heat treatment process;

(ii) Type of heat treatment;

(iii) Conditions of heat treatment, including time, temperature, and moisture; and

(iv) Method validation data, including microbial loads (including bacteria, spores, yeast and fungi) and tobacco-specific nitrosamines (TSNAs) before and after heat treatment.

(f) *Shelf life and stability information*. With the exception of SE Reports for roll-your-own tobacco products and cigarettes that are not HTPs, SE Reports for all tobacco products must contain information on the stability of the new and predicate tobacco products over the shelf life, including the following information:

(1) The length of the shelf life, a description of how shelf life is determined, and a description of how shelf life is indicated on the tobacco product, if applicable. If a tobacco product does not have a defined shelf life, state as such.;

(2) Any known or expected impacts of the differences between the new and predicate products on the product stability. If no impact is known or expected, state that;

(3) Stability data assessed at the beginning (zero time), middle, and end of the expected shelf life. If a tobacco product does not have a defined shelf life, provide stability data over a specified amount of time and a justification for why that time period is appropriate. Stability testing must be performed for the microbial and chemical endpoints as follows:

(i) Microbial content data including total aerobic microbial count and total yeast and mold count;

(ii) Water activity; and

(iii) Tobacco-specific nitrosamine yields (total, N-nitrosonornicotine (NNN), and 4-methylnitrosamino)-1-(3-pydridyl)-1-butanone) (NNK)).

(4) Stability testing details for each microbial and chemical endpoint, including:

(i) The mean quantity and variance with unit of measure;

(ii) The number of samples and measurement replicates for each sample;

(iii) The methods used, associated reference(s), and full validation reports for each method (as applicable);

(iv) The testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(v) Length of time between dates of tobacco product manufacture and date(s) of testing;

(vi) Storage conditions of the tobacco products before they were tested;

(vii) A statement that the testing was performed on a tobacco product in the same container closure system in which the tobacco product is intended to be marketed; and

(viii) Full test data (including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria, complete data sets, and a summary of the results) for all stability testing performed.

(g) *Applicant's basis for substantial equivalence determination*. The applicant must state that the new tobacco product has either:

(1) The same characteristics as the predicate tobacco product and the basis for this determination, or

(2) Different characteristics than the predicate tobacco product. Where an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: Product design (paragraph (a) of this section); heating source (paragraph (b) of this section); materials and ingredients (paragraph (c) of this section); and other features (paragraph (d) of this section). In addition, to demonstrate that a new tobacco product is substantially equivalent, an applicant must also explain why any differences in the manufacturing process between the new tobacco product and the predicate tobacco product would not change the characteristics of the new tobacco product such that the new tobacco product could raise different questions of public health (§ 1107.18(e)). Similarly, for smokeless tobacco products and tobacco products that contain fermented tobacco, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not cause the new tobacco product to raise different questions of public health (paragraph (f) of this section).

(h) *Comparison to original predicate tobacco product*. If the applicant is comparing the new tobacco product to a predicate tobacco product that FDA has previously found to be substantially equivalent, FDA may request that the applicant include information related to the original predicate tobacco product that was commercially marketed (other than for test

marketing) in the United States as of February 15, 2007, even if that original predicate tobacco product is back several predicate tobacco products. FDA will request this information when necessary to ensure that any order the Agency issues finding the new tobacco product substantially equivalent complies with section 910(a)(2)(A)(i)(I) of the Federal Food, Drug, and Cosmetic Act. FDA may need to review the first SE Report that received a finding of substantial equivalence using the original predicate tobacco product as a predicate tobacco product in order to make this finding.

§ 1107.20 Amendments.

(a) Except as provided in paragraphs (b) and (c) of this section, the applicant may submit an amendment to an SE Report in accordance with subpart C of this part. If an applicant chose to submit a health information summary with its SE Report under § 1107.18(j)(1), the applicant must submit with the amendment a redacted copy of the amendment that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter.

(b) An applicant may not amend an SE Report to change the predicate tobacco product.

(c) An applicant may not amend an SE Report after FDA has closed the SE Report under § 1107.44 or it has been withdrawn under § 1107.22.

(d) In general, amendments will be reviewed in the next review cycle as described in § 1107.42.

§ 1107.22 Withdrawal by applicant.

(a) An applicant may at any time make a written request to withdraw an SE Report for which FDA has not issued an order. The withdrawal request must state:

(1) Whether the withdrawal is due to a health or safety concern related to the tobacco product;

(2) The submission tracking number; and

(3) The name of the new tobacco product that is the subject of the SE Report.

(b) An SE Report will be considered withdrawn when FDA issues a notice stating the SE Report has been withdrawn.

(c) The SE Report is an Agency record, even if withdrawn. FDA will retain the withdrawn SE Report under Federal Agency records schedules. The availability of the withdrawn SE Report will be subject to FDA's public information regulations in part 20 of this chapter.

§ 1107.24 Change in ownership of an SE Report.

An applicant may transfer ownership of its SE Report. On or before the time of transfer, the new and former applicants are required to submit information to FDA as follows:

(a) The former applicant must sign and submit a notice to FDA that states that all of the former applicant's rights and responsibilities relating to the SE Report have been transferred to the new applicant. This notice must identify the name and address of the new applicant and the SE Report transferred.

(b) The new applicant must sign and submit a notice to FDA containing the following:

(1) The new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the SE Report;

(2) The date that the change in ownership is effective;

(3) Either a statement that the new applicant has a complete copy of the SE Report and order (if applicable), including amendments and records that are required to be kept under § 1107.58, or a request for a copy of the SE Report from FDA's files by submitting a request in accordance with part 20 of this chapter. In accordance with the Freedom of Information Act, FDA will provide a copy of the SE Report to the new applicant under the fee schedule in FDA's public information regulations in § 20.45 of this chapter; and

(4) A certification that no modifications have been made to the new tobacco product since the SE Report was submitted to FDA.

Subpart D--FDA Review

§ 1107.40 Communications between FDA and applicants.

(a) *General principles*. During the course of reviewing an SE Report, FDA may communicate with applicants about relevant matters, including scientific, medical, and procedural issues that arise during the review process. These communications may take the form of telephone conversations, letters, or emails, and will be documented in the SE Report in accordance with § 10.65 of this chapter.

(b) *Meeting*. Meetings between FDA and applicants may be held to discuss scientific and other issues. Requests for meetings will be directed to the Office of Science, Center for Tobacco Products, and FDA will make every attempt to grant requests for meetings that involve important issues.

(c) *Acceptance of an SE Report for review*. After receiving an SE Report under § 1107.18, FDA will either refuse to accept the SE Report for review or issue an acceptance for review letter.

(d) *Notification of deficiencies in an SE Report submitted under § 1107.18*. FDA will make reasonable efforts to communicate to applicants the procedural, administrative, or scientific deficiencies found in an SE Report and any additional information and data needed for the Agency's review. The applicant must also provide additional comparison information under § 1107.19 if requested by FDA.

(e) *Withdrawal of SE Report*. An SE Report will be considered withdrawn when FDA issues a notice stating that the SE Report has been withdrawn.

§ 1107.42 Review cycles.

(a) *Initial review cycle*. FDA intends to review the SE Report and either communicate with the applicant as described in § 1107.40 or take an action under § 1107.44 within 90 calendar days of FDA's receipt of the SE Report, or within 90 calendar days of determining that the predicate was found to be commercially marketed (other than for test marketing) in the United

States as of February 15, 2007 (if applicable), whichever is later. This 90-day period is called the "initial review cycle."

(b) *Additional review cycles*. If FDA issues a deficiency notification under § 1107.40(d) during the initial review cycle, FDA will stop reviewing the SE Report until it receives a response from the applicant or the timeframe specified in the notification of deficiencies for response has elapsed. If the applicant fails to respond within the time period provided in the notification of deficiency, FDA will issue an order denying marketing authorization under the criteria set forth in § 1107.48. If the applicant's response to the notification of deficiencies provides the information FDA requested, but FDA identifies additional deficiencies, FDA may issue an additional deficiency notification. Each response will begin a new 90-day review cycle.

(c) *Inadequate response*. If the applicant's response to FDA's deficiency notification(s) does not provide the information FDA requested, or the applicant provides information but the SE Report is still deficient, FDA generally intends to issue an order denying market authorization under the criteria set forth in § 1107.48. At any time before FDA issues an order, an applicant may make a written request to withdraw an SE Report under § 1107.22.

§ 1107.44 FDA action on an SE Report.

After receipt of an SE Report, FDA will:

(a) Refuse to accept the SE Report for review if it does not comply with § 1107.18 and § 1105.10 of this chapter;

(b) Request additional information as provided in § 1107.40(d);

(c) Issue a letter administratively closing the SE Report if it is not possible to make a determination on an SE Report;

(d) Issue a letter canceling the SE Report if FDA finds the SE Report was created in error;

(e) Issue an order as described in § 1107.46 finding the new tobacco product to be substantially equivalent and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act; or

(f) Issue an order as described in § 1107.48 denying marketing authorization because the new tobacco product is:

(1) Not substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States on February 15, 2007, or

(2) Not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.

§ 1107.46 Issuance of an order finding a new tobacco product substantially equivalent.

If FDA finds that the information submitted in the SE Report establishes that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed (other than for test marketing) in the United States on February 15, 2007, and finds that the new tobacco product is in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, FDA will send the applicant an order authorizing marketing of the new tobacco product. A marketing authorization order becomes effective on the date the order is issued.

§ 1107.48 Issuance of an order denying marketing authorization.

(a) *General*. FDA will issue an order that the new tobacco product cannot be marketed if FDA finds that:

(1) The information submitted in the SE Report does not establish that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed (other than for test marketing) in the United States on February 15, 2007; or

(2) The new tobacco product is not in compliance with the Federal Food, Drug, and Cosmetic Act.

(b) *Basis for order*. The order will describe the basis for denying marketing authorization.

§ 1107.50 Rescission of order.

(a) *Grounds for rescinding a substantially equivalent order*. FDA may rescind a substantially equivalent order allowing a new tobacco product to be marketed if FDA determines that:

(1) The tobacco product for which the order has been issued:

(i) Does not have the same characteristics as the predicate tobacco product; or

(ii) Has different characteristics and there is insufficient information demonstrating that it is not appropriate to require a premarket tobacco product application under section 910(b) of the Federal Food, Drug, and Cosmetic Act because the product does not raise different questions of public health; or

(2) The SE Report (including any submitted amendments) contains an untrue statement of material fact; or

(3) Concerning an SE Report that compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent,

(i) The predicate tobacco product relied on in the SE Report has been found ineligible because its SE Report (including any amendments) contains an untrue statement of material fact; or

(ii) A predicate tobacco product on which any of the previous substantial equivalence determinations was based, going back to the original predicate tobacco product, has been found ineligible because its SE Report (including any amendments) contains an untrue statement of material fact; or

(4) FDA or the applicant has removed from the market, due to a health or safety concern related to the tobacco product:

(i) The predicate tobacco product on which the substantial equivalence determination is based; or

(ii) A predicate tobacco product on which any of the previous substantial equivalence determinations is based, going back to the original predicate tobacco product, if the substantial equivalence SE Report compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent.

(b) *Opportunity for a hearing*. (1) Except as provided in paragraphs (b)(2) and (3) of this section, FDA will rescind an order only after notice and opportunity for a hearing under part 16 of this chapter.

(2) FDA may rescind a substantially equivalent order prior to notice and opportunity for a hearing under part 16 of this chapter if it finds that there is a reasonable probability that continued marketing of the tobacco product presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

(3) FDA may rescind a substantially equivalent order without notice and opportunity for a hearing under part 16 of this chapter if the applicant has notified the Agency of a mistake in the application, FDA has determined that the mistake is part of the underlying scientific determination of the order which makes the order invalid, and the applicant has agreed that FDA can rescind the order without providing notice and opportunity for a hearing under part 16 of this chapter.

Subpart E--Miscellaneous

§ 1107.58 Record retention.

Each applicant that receives an order under § 1107.46 authorizing the marketing of a new tobacco product must maintain all records required by this subpart and that support the SE Report for a substantial equivalence order. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. All records must be retained for a period of not less than 4 years from the date of the order even if such product is discontinued.

§ 1107.60 Confidentiality.

(a) *General*. FDA will determine the public availability of any part of an SE Report and other content related to such an SE Report under this section and part 20 of this chapter.

(b) *Confidentiality of data and information prior to an order*. Prior to issuing an order under this section:

(1) FDA will not publicly disclose the existence of an SE Report unless:

(i) The tobacco product has been introduced or delivered for introduction into interstate commerce for commercial distribution; or

(ii) The applicant has publicly disclosed or acknowledged the existence of the SE Report (as such disclosure is defined in § 20.81 of this chapter), or has authorized FDA in writing to publicly disclose or acknowledge, that the applicant has submitted the SE Report to FDA.

(2) FDA will not disclose the existence of or contents of an FDA communication with an applicant regarding its SE Report except to the extent that the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of or contents of that particular FDA communication.

(3) FDA will not disclose information contained in an SE Report unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information contained in an SE Report, FDA may disclose that particular information.

(c) *Disclosure of data and information after issuance of an order under § 1107.46*. After FDA issues an order under § 1107.46 finding a new tobacco product substantially equivalent, it will make the following information related to the SE Report and order available for public disclosure upon request or at FDA's own initiative, including information from amendments to the SE Report and FDA's reviews of the SE Report:

(1) All data previously disclosed to the public, as such disclosure is defined in § 20.81 of this chapter;

(2) Any protocol for a test or study, except to the extent it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter;

(3) Information and data submitted to demonstrate that the new tobacco product does not raise different questions of public health, except to the extent it is shown to fall within the exemptions established in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy;

(4) Correspondence between FDA and the applicant, including any requests FDA made for additional information and responses to such requests, and all written summaries of oral discussions between FDA and the applicant, except to the extent it is shown to fall within the exemptions in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy; and

(5) In accordance with § 25.51 of this chapter, the environmental assessment or, if applicable, the claim of categorical exclusion from the requirement to submit an environmental assessment under part 25 of this chapter.

(d) *Disclosure of data and information after issuance of an order under § 1107.48*. After FDA issues an order under §1107.48 (denying marketing authorization), FDA may make certain information related to the SE Report and the order available for public disclosure upon request or at FDA's own initiative except to the extent the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes the tobacco product category (e.g., cigarette), tobacco product subcategory (e.g., filtered), package size, and the basis for the order denying marketing authorization.

(e) *Health information summary or statement*. Health information required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, if submitted as part of the SE Report

(which includes any amendments), will be disclosed within 30 calendar days of issuing a substantially equivalent order. If the applicant has instead submitted a 910(a)(4) statement as provided in § 1107.18(j)(2), FDA will make publicly available on FDA's website the responsible official to whom a request for health information may be made.

§ 1107.62 Electronic submission.

(a) *Electronic format requirement*. Applicants submitting any documents to the Agency under this part must provide all required information to FDA using the Agency's electronic system, except as provided in paragraph (b) of this section. The SE Report and all supporting information must be in an electronic format that FDA can process, read, review, and archive.

(b) *Waivers from electronic format requirement*. An applicant may submit a written request that is legible and written in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants can send the written request to the address included on our website (www.fda.gov/tobaccoproducts). The request must include the following information:

(1) The name and address of the applicant, list of individuals authorized for the applicant to serve as the contact person, and contact information including an email address. If the applicant has submitted an SE Report previously, the regulatory correspondence must also include any identifying information for the previous submission.

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the person requesting the waiver, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by the applicant or by an employee of the applicant who is authorized to make the declaration on behalf of the applicant.

(c) *Paper submission*. An applicant who has obtained a waiver from filing electronically must send a written SE Report through the Document Control Center to the address provided in the FDA documentation granting the waiver.

Dated: January 13, 2021 .

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

Dated: January 11, 2021.

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Stephen M. Hahn,

Commissioner of Food and Drugs.

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