



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1105

[Docket No. FDA-2016-N-1555]

Refuse to Accept Procedures for Premarket Tobacco Product Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule describing when FDA would refuse to accept a tobacco product submission (or application) because the application has not met a minimum threshold for acceptability for FDA review. Under the proposed rule, FDA would refuse to accept a tobacco product submission, for example, that is not in English, does not pertain to a tobacco product, or does not identify the type of submission. By refusing to accept submissions that have the deficiencies identified in the proposed rule, FDA would be able to focus our review resources on submissions that meet a threshold of acceptability and encourage quality submissions. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-1555 for "Refuse to Accept Procedures for Premarket Tobacco Product Submissions." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler or Paul Hart, Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing this refuse to accept rule as a companion to the direct final rule issued elsewhere in this issue of the Federal Register. The proposed rule would identify deficiencies that would result in FDA's refusal to accept certain tobacco product submissions under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)(21 U.S.C. 387e, 387j, and 387k).¹ Because these submissions would be refused before they enter FDA's review queue, more resources would be available for submissions that are ready for further review. This proposed rule would establish a refuse to accept process for premarket tobacco

¹ FDA has published a final rule extending the Agency's "tobacco product" authorities in the FD&C Act to all categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products (Final Rule 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)). This proposed rule would apply to all tobacco products FDA regulates under Chapter IX of the FD&C Act.

product submissions, including premarket tobacco product applications (PMTAs), modified risk tobacco product applications (MRTPAs), substantial equivalence (SE) applications (also called SE reports), and exemption requests (including subsequent abbreviated reports).

B. Summary of the Major Provisions of the Regulatory Action

The proposed rule explains when FDA would refuse to accept a premarket submission, including PMTAs, MRTPAs, SE applications, and exemption requests (including subsequent abbreviated reports). The proposal is based on FDA's experience in reviewing these submissions. Under the proposed rule, FDA would refuse to accept a premarket submission that: (1) Does not pertain to a tobacco product; (2) is not in English (or does not include a complete translation); (3) is submitted in an electronic format that FDA cannot process, read, review, or archive; (4) does not include the applicant's contact information; (5) is from a foreign applicant and does not include the name and contact information of an authorized U.S. agent (authorized to act on behalf of the applicant for the submission); (6) does not include a required form(s); (7) does not identify the tobacco product; (8) does not identify the type of submission; (9) does not include the signature of a responsible official authorized to represent the applicant; or (10) does not include an environmental assessment or claim of a categorical exclusion, if applicable. Under the proposed rule, if FDA refuses to accept the submission, FDA would send the contact (if available) a notification. If the submission is accepted for further review, FDA would send an acknowledgement letter.

II. Direct Final Rulemaking

This proposed rule is a companion to the direct final rule with the same codified language published in the final rules section of this issue of the Federal Register. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct

final rule receives any adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. We are publishing the direct final rule because the rule is noncontroversial, and we do not anticipate that it will receive any significant adverse comments.

An adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice and comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment unless the comment provides a reasonable explanation for why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule, and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not subjects of significant adverse comment.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document, before the effective date of the direct final rule, confirming that the direct final rule will go into effect on [INSERT DATE 135 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. In the Federal Register of November 21, 1997 (62 FR 62466), you can find additional information about direct rulemaking procedures in the guidance document

entitled "Guidance for FDA and Industry: Direct Final Rule Procedures." This guidance may be accessed at <http://www.fda.gov/regulatoryinformation/guidances/ucm125166.htm>.

III. Purpose and Legal Authority

A. Purpose

FDA is proposing this rule as a means of efficiently handling submissions that do not meet a threshold of acceptability for FDA review, e.g., the submission lacks certain information FDA needs for substantive review of the submission. Currently, FDA often expends extensive time and resources in attempts to obtain information and resolve the deficiencies identified in the proposed rule simply to begin substantively processing the submission. FDA expects that this proposed rule would enhance the quality of the submissions and that submissions would move expeditiously through the review process. In addition, this rule would help submitters better understand the common hurdles FDA encounters in conducting a substantive review of submissions.

The proposed rule identifies deficiencies that FDA has seen across types of premarket submissions and would result in FDA refusing to accept the submission. This proposed rule applies to all tobacco product applications; we note that there are additional deficiencies that are not covered in this rule that may arise for specific types of premarket submissions that would also result in FDA's refusal to accept that specific type of premarket submission (e.g., a PMTA fails to contain specimens of the labeling proposed to be used for such tobacco product under section 910(b)(1)(F) of the FD&C Act).

FDA's refusal to accept a tobacco product submission would not preclude an applicant from resubmitting a new submission that addresses the deficiencies. In addition, acceptance of a submission would not mean that FDA has determined that the submission is complete, but rather

only that the submission has met the basic, minimum threshold for acceptance. Substantive review of the submission would begin once FDA accepts the submission, and for submissions with filing requirements (i.e., PMTAs and MRPTAs), once filed. This proposed rule would establish a general process for refusing to accept submissions for premarket tobacco review, including PMTAs, MRTPAs, SE applications, and exemption requests (including subsequent abbreviated reports). Because administratively incomplete submissions would be refused before FDA begins substantive review, we would be able to use our resources on submissions that are more complete and better prepared for further review. In addition, FDA intends to determine, as soon as practicable, whether the submission will be accepted. We expect the amount of time it takes FDA to make this determination to be relatively quick, however, it may vary depending on the volume of submissions received at any one time. FDA remains committed to an efficient product review process and intends to establish and implement performance goals for this action once it has experience with the volume of submissions it will receive after the deeming rule becomes effective. FDA expects the performance goals to be generally similar to other Agency performance goals, i.e. a certain percentage of RTA determinations made within a defined period of time, and with the percentage rising over time.

B. Legal Authority

Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) provides FDA with the authority to issue regulations for the efficient enforcement of the FD&C Act. This proposed rule would allow FDA to more efficiently use our resources to review premarket submissions under sections 905, 910, and 911 of the FD&C Act. FDA has processed and reviewed many submissions since the enactment of the Tobacco Control Act, and submissions with the deficiencies identified in

the proposed rule have been repeatedly identified by FDA as reflecting submissions that are incomplete and not prepared for further review.

IV. Description of Proposed Regulation

We are proposing to add part 1105 (21 CFR part 1105) to title 21, specifically § 1105.10. Proposed § 1105.10(a) would provide that FDA would refuse to accept, as soon as practicable, PMTAs, MRTPAs, SE applications, and exemption requests (including subsequent abbreviated reports) for the reasons listed in paragraphs (a)(1) through (a)(10), if applicable.

- Proposed § 1105.10(a)(1) states that FDA would refuse to accept a submission that does not pertain to a tobacco product. This provision would address a submission that refers to a product that does not meet the definition of a "tobacco product" under section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) and, therefore, would not be subject to FDA's tobacco product authorities.
- Proposed § 1105.10(a)(2) states that FDA would refuse to accept a submission that is not in the English language or does not contain complete English translations of any information included with the submission. FDA is unable to read and process such submissions.
- Proposed § 1105.10(a)(3) provides that FDA would refuse to accept a submission if it is provided in an electronic format that FDA cannot process, read, review, and archive. As with submissions that are not in English (or fail to include an English translation), FDA is unable to read and process such a submission. FDA provides information on the electronic formats that it can read, process, review, and archive at <http://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/manufacturing/default.htm>.

- Proposed § 1105.10(a)(4) provides that FDA would refuse to accept any submission that does not contain contact information, including the applicant's name and address. If a submission omits the contact information, FDA would not be able to contact the applicant regarding the submission, e.g., with questions or followup related to the submission. In this instance, FDA also would likely be unable to provide notice of the Agency's refusal to accept the submission under § 1105.10(c).
- Proposed § 1105.10(a)(5) provides that FDA would refuse to accept a submission from a foreign applicant if it does not list an authorized U.S. agent for the submission, including the agent's U.S. address. FDA is proposing to require identification of a U.S. agent for two reasons: First, a U.S. agent is important to help CTP ensure adequate notice is provided to applicants for official Agency communications. FDA may be unable to confirm that adequate notice of Agency action or correspondence concerning premarket submissions is provided to foreign applicants as FDA cannot necessarily confirm receipt of correspondence sent internationally. Accordingly, the designation of a U.S. agent provides an official contact to the Agency who can receive the information or documentation on behalf of the applicant. Providing notice regarding that application to the U.S. agent would constitute notice to the foreign applicant. Second, FDA requires identification of a U.S. agent to assist FDA in communication with the foreign applicant and help the Agency to efficiently process applications and avoid delays. In many instances during the application review process, FDA has reached out numerous times to foreign applicants and has either been unable to speak with the applicant or unable to directly communicate questions and/or concerns. This impediment, which occurs more for foreign applicants than domestic applicants, has resulted in delays or terminations in

the review of specific applications and a slowdown of the premarket application process as a whole. A U.S. agent would act as a communications link between FDA and the applicant and would facilitate timely correspondence between FDA and foreign applicants, including responding to questions concerning pending applications and, if needed, assisting FDA in scheduling meetings with the foreign applicants to resolve outstanding issues before Agency action is taken. Additionally, the identified U.S. agent would be authorized to act on behalf of the foreign applicant for that specific application.

- Proposed § 1105.10(a)(6) provides that FDA would refuse to accept the submission if it does not include any required FDA form(s). At the time of this proposed rule, FDA has not yet issued any forms to accompany premarket submissions. In the event that FDA does issue such a form(s), the Agency will give interested parties notice and opportunity to comment on such forms in accordance with rulemaking procedures and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).
- Proposed § 1105.10(a)(7) provides that FDA would refuse to accept a submission that does not contain the following product-identifying information (for the product that is the subject of the submission and, if applicable, for the predicate): The manufacturer of the tobacco product; the product name, including brand and subbrand; product category (e.g., cigarette) and subcategory (e.g., combusted, filtered); package type (e.g., box) and package quantity (e.g., 20 per box); and characterizing flavor (i.e., applicants must state the characterizing flavor, such as menthol, or state that there is no characterizing flavor present in the tobacco product). For example, in table 1, FDA has supplied a list of recommended categories and subcategories of some tobacco products to assist applicants in providing product-identifying information in their submissions. Note that there may

be other information FDA needs to identify a particular product, e.g., descriptors (such as "premium") that are separate from the product name. If this is the case, such information should be provided by the applicant in the initial submission to facilitate FDA's efficient review.

Table 1.--Tobacco Products Categories and Subcategories

Tobacco Product Category	Tobacco Product Subcategory
Cigarettes	Combusted, Filtered Combusted, Non-Filtered Combusted, Other Non-Combusted
Roll-Your-Own Tobacco Products	Roll-Your-Own Tobacco Filler Rolling Paper Filtered Cigarette Tube Non-Filtered Cigarette Tube Filter Paper Tip Roll-Your-Own Co-Package Other
Smokeless Tobacco Products	Loose Moist Snuff Portioned Moist Snuff Loose Snus Portioned Snus Loose Dry Snuff Dissolvable Loose Chewing Tobacco Portioned Chewing Tobacco Smokeless Co-Package Other
ENDS (Electronic Nicotine Delivery System)	Open E-Liquid Closed E-Liquid Closed E-Cigarette Open E-Cigarette ENDS Component ENDS Co-Package ENDS Other
Cigars	Filtered, Sheet-Wrapped Cigar Unfiltered, Sheet-Wrapped Cigar Leaf-Wrapped Cigar Cigar Component Cigar Tobacco Filler Cigar Co-Package Other
Pipe Tobacco Products	Pipe Pipe Tobacco Filler Pipe Component Pipe Co-Package Other

This product-specific information helps ensure that the product is within CTP's purview and enables FDA to appropriately identify the specific product that is the subject of the submission. Specifically, this information is necessary to both review the submission itself and to issue an order that appropriately identifies the tobacco product that is subject to the order. For example, an SE submission contains a comparison between the predicate and new products. If FDA does not know the exact products that are being compared, FDA would be unable to sufficiently understand and evaluate the comparison to determine whether the products are substantially equivalent. As another example, if an applicant does not specify whether its proposed new product contains a characterizing flavor, FDA would not be able to issue an order as it will not know the specific product for which the applicant is seeking an order (e.g., product X menthol or product X cinnamon.)

- Proposed § 1105.10(a)(8) provides that FDA would refuse to accept a submission if the applicant fails to indicate the type of submission (i.e., PMTA, MRTPA, SE application, or exemption request or subsequent abbreviated report), because that information is necessary to enable FDA to begin an appropriate review of the submission.
- Proposed § 1105.10(a)(9) provides that FDA would refuse to accept a submission if it does not contain a signature of a responsible official, authorized to represent the applicant who either resides in or has a place of business in the United States. A signature provides assurance to FDA that the submission is both intended by the applicant and ready for review. Responsible officials also should be aware that under 18 U.S.C. 1001, it is illegal to knowingly and willingly submit false information to the U.S. Government.

- Proposed § 1105.10(a)(10) would apply only to PMTAs, MRTPAs, SE applications, and exemption requests (this subsection does not apply to the subsequent abbreviated report). For these submissions, this proposed paragraph provides that FDA would refuse to accept the submission if it does not include an environmental assessment (EA) or a valid claim of categorical exclusion prepared in accordance with 21 CFR 25.40. Under § 25.15(a) (21 CFR 25.15), all submissions requesting FDA action require the submission of either a claim of categorical exclusion or an EA. Because an EA is required for an initial exemption request, it is not also required for an abbreviated report, and thus would not be a basis for FDA to refuse to accept an abbreviated report. In addition, § 25.15(a) provides that FDA may refuse to file a submission if the included EA fails to address "the relevant environmental issues." Because the SE and SE Exemption pathways do not include a filing stage, FDA intends to determine such adequacy at the acceptance stage for those pathways.² The EA or claim of categorical exclusion must be made for the Agency action being proposed (e.g., issuance of an SE order for introduction of such new tobacco product into interstate commerce for commercial distribution in the United States.). For information on preparing an EA, refer to § 25.40.

Proposed § 1105.10(b) provides that if FDA does not identify a reason under paragraph (a) for refusing to accept a premarket review submission, then the Agency may accept it for processing and further review. If FDA does accept the submission, the Agency intends to send the submitter an acknowledgement letter stating that FDA has accepted the submission for processing and further review. This letter would also include a premarket submission tracking number.

² The PMTA and MRTPA pathways, by contrast, have a filing stage.

Proposed § 1105.10(c) provides that if FDA identifies a reason under paragraph (a) for refusing to accept a premarket review submission, we would notify the applicant in writing of the reason(s) and that FDA has not accepted the submission for processing and further review. However, FDA would not be able to provide this information when the contact information has not been provided or is not legible. If FDA would refuse to accept the submission for one or more of the reasons stated in § 1105.10, the submitter may revise the submission to correct the deficiencies and resubmit it to FDA as a new submission.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VII. Tribal Consultation

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that would 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; consequently, a tribal summary impact statement is not required.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, 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). We believe that this proposed rule is not 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 this proposed rule would establish a procedure that FDA would be responsible for implementing and would have the effect of providing all entities useful feedback on the readiness of a submission, we certify that the proposed 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 \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in expenditure in any year that meets or exceeds this amount.

This proposed rule identifies 10 significant and common deficiencies in premarket tobacco submissions that will cause FDA to refuse to accept them. Encouraging submissions that are free of the deficiencies listed in this rule does not represent a change in Agency expectations. One of the 10 deficiencies is required by statute (i.e., must be a tobacco product). One of the deficiencies is required by another regulation (i.e., must comply with environmental considerations). The remaining eight deficiencies are basic expectations for an application to enter the review process. Therefore, this proposed rule would clarify these expectations. This clarification would result in cost savings for both the applicant and FDA as less time is spent by FDA working with applicants to address these significant deficiencies. Applicants would have clarity about basic expectations of the requirements needed for acceptance of premarket applications. In addition, refusing to accept submissions with these deficiencies would allow Agency staff to more efficiently process submissions and quickly move those submissions without these deficiencies into review of substantial scientific issues.

List of Subjects in 21 CFR Part 1105

Administrative practices and procedures, Tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is proposed to be amended by adding part 1105.

PART 1105--GENERAL

Sec

1105.10 Refusal to accept a premarket submission

Authority: 21 U.S.C. 371(a), 387e, 387j, and 387k.

Subpart A--General Submission Requirements

§ 1105.10 Refusal to accept a premarket submission.

(a) FDA will refuse to accept for review, as soon as practicable, a premarket tobacco product application, modified risk tobacco product application, substantial equivalence application, or exemption request or subsequent abbreviated report for the following reasons, if applicable:

- (1) The submission does not pertain to a tobacco product as defined in 21 U.S.C. 321(rr).
- (2) The submission is not in English or does not contain complete English translations of any information submitted within.
- (3) If submitted in an electronic format, the submission is in a format that FDA cannot process, read, review, and archive.
- (4) The submission does not contain contact information, including the applicant's name and address.
- (5) The submission is from a foreign applicant and does not identify an authorized U.S. agent, including the agent's name and address, for the submission.
- (6) The submission does not contain a required FDA form(s).

(7) The submission does not contain the following product-identifying information: The manufacturer of the tobacco product; the product name, including the brand and subbrand; the product category and subcategory; package type and package quantity; and characterizing flavor.

(8) The type of submission is not specified.

(9) The submission does not contain a signature of a responsible official, authorized to represent the applicant, who either resides in or has a place of business in the United States.

(10) For premarket tobacco applications, modified risk tobacco product applications, substantial equivalence applications, and exemption requests only: The submission does not include an environmental assessment, or a valid claim of categorical exclusion in accordance with part 25 of this chapter.

(b) If FDA finds that none of the reasons in paragraph (a) of this section exists for refusing to accept a premarket submission, FDA may accept the submission for processing and further review. FDA will send to the submitter an acknowledgement letter stating the submission has been accepted for processing and further review and will provide the premarket submission tracking number.

(c) If FDA finds that any of the reasons in paragraph (a) of this section exist for refusing to accept the submission, FDA will notify the submitter in writing of the reason(s) and that the submission has not been accepted, unless insufficient contact information was provided.

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-18533 Filed: 8/5/2016 8:45 am; Publication Date: 8/8/2016]