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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1150

[Docket No. FDA-2012-N-0920]

RIN 0910-AG81

Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA recently expanded its authority by issuing a 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" (Deeming rule), deeming all products that meet the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the FD&C Act. The Deeming rule, among other things, subjected domestic manufacturers and importers of cigars and pipe tobacco to the FD&C Act's user fee requirements. Consistent with the Deeming rule and the requirements of the FD&C Act, this final rule requires the submission of the information

needed to calculate user fee assessments for each manufacturer and importer of cigars and pipe tobacco to FDA.

DATES: This rule is effective [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Domestic manufacturers and importers of cigars and pipe tobacco must begin submitting data required by § 1150.5 (21 CFR 1150.5) to FDA no later than the 20th day of August, 2016.

Because FDA can perform class allocations only on a full fiscal year basis, domestic manufacturers and importers of cigars and pipe tobacco will become subject to user fee assessments on October 1 of the first full fiscal year following the effective date of this rule.

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I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009 (Pub. L. 111-31), amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 101(b) of the Tobacco Control Act amends the FD&C Act by adding chapter IX (sections 900 through 920 (21 U.S.C. 387 through 387u)). Chapter IX provides FDA with tools and funds to regulate tobacco products and imposes certain obligations on domestic tobacco product manufacturers and importers. Included among FDA's authorities are the authorities to assess and collect user fees.

In enacting the Tobacco Control Act, Congress found that tobacco use is the single most preventable cause of disease, disability, and death in the United States. Each year, over 400,000 people die prematurely from smoking or exposure to secondhand smoke. Approximately 8.6 million people in the United States live with a serious illness caused by smoking. A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects (sections 2(2), (3), and (13) of the Tobacco Control Act).

The Tobacco Control Act grants FDA the authority to regulate tobacco products and to protect the public from the harmful effects of tobacco use. Section 901(b) of the FD&C Act automatically provides that chapter IX applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. It also permits FDA to issue a regulation to deem other tobacco products subject to the FD&C Act, which FDA has done, by publishing elsewhere in this issue of the Federal Register, the Deeming rule to bring all products meeting the definition of tobacco

product under its FD&C Act authority. More specifically, the Tobacco Control Act gives FDA the authority to, among other things:

- Restrict tobacco product retail sales to youth;
- require owners and operators of tobacco companies to register annually and be subject to biennial inspection by FDA (section 905 of the FD&C Act);
- require manufacturers and importers who wish to market a new tobacco product to obtain a marketing order from FDA prior to marketing that product (section 910 of the FD&C Act);
- require each manufacturer or importer to report all constituents, including smoke constituents as applicable, identified by FDA as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand (section 904(a)(3) of the FD&C Act);
- establish tobacco product standards if FDA finds that it is appropriate for the protection of the public health (section 907(a)(3) of the FD&C Act);
- conduct compliance-check inspections of tobacco product retailers to determine a retailer's compliance with Federal laws and regulations;
- establish science and research programs to inform the development of tobacco product regulations and better understand the risks associated with tobacco use;
- educate the public about the harmful effects of tobacco use; and
- assess and collect user fees from each domestic manufacturer and importer of tobacco products subject to section 919 of the FD&C Act.

Section 919(c)(2) of the FD&C Act provides that tobacco product user fees are the sole source of funding for FDA's regulation of tobacco products. Therefore, FDA considers these

fees to be critical to the Agency's ability to achieve its mission to protect and promote the public health. User fees provide FDA with a source of stable, consistent funding that has made possible our implementation of the Tobacco Control Act. The revenues from these fees fund the Agency's regulation of tobacco products and the tobacco industry, as described previously.

In the Federal Register of May 31, 2013 (78 FR 32581), FDA issued a notice of proposed rulemaking (User Fee proposed rule) to add 21 CFR part 1150 to require domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the FD&C Act. FDA finalized portions of the User Fee proposed rule relating to tobacco products under FDA's jurisdiction at that time in the final rule "Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products," which was published in the Federal Register of July 10, 2014 (79 FR 39302) (User Fee final rule). Elsewhere in this issue of the Federal Register, FDA is publishing the Deeming rule to deem all products meeting the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the FD&C Act. This rule is being issued in response to FDA's user fee authority over cigars and pipe tobacco, and finalizes portions of the User Fee proposed rule that relate to domestic manufacturers and importers of cigars and pipe tobacco, requiring them to submit information needed to calculate user fee assessments to FDA.

The final rule, issued under section 919(a) of the FD&C Act, requires FDA to assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to chapter IX of the FD&C Act. The total amount of user fees for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and under section 919(a) we are to assess and collect a proportionate amount each quarter of the fiscal year. The FD&C Act provides for the total

assessment to be allocated among the classes of tobacco products identified in the statute: Cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. The class allocation is based on each tobacco product class' volume of tobacco products removed[1] into commerce that is not exempt from certain taxes. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its statutorily defined "percentage share" for that tobacco product class.

In specifying how to determine each of these two allocations--to a class of tobacco products and then to a domestic manufacturer or importer within a particular class of tobacco products--section 919 of the FD&C Act references the Fair and Equitable Tobacco Reform Act of 2004 (FETRA, Pub. L. 108-357 (7 U.S.C. 518 et seq.)). In determining the user fees to be allocated to each class of tobacco products, section 919(b)(2)(B)(ii) of the FD&C Act provides that the applicable percentage for each tobacco product class shall be the percentage determined under section 625(c) of FETRA for each such class of product for such fiscal year. The classes of tobacco products identified in section 919 of the FD&C Act are the same classes subject to assessments under FETRA. In determining the user fee to be paid by each company within a given class, except the cigar class, section 919(b)(4) of the FD&C Act directs that we use percentage share information determined for purposes of allocations under paragraphs (e) through (h) of section 625 of FETRA. With regards to cigars, section 919(b)(5) of the FD&C Act directs that the percentage share for each domestic manufacturer and importer be based on the excise taxes paid during the prior fiscal year, rather than the prior quarter.

[1] Removal is defined at 26 U.S.C. 5702 as the removal of tobacco products or cigarette papers or tubes, or any processed tobacco, from the factory or from internal revenue bond under section 5704, as the Secretary of Treasury shall by regulation prescribe, or release from customs custody, and shall also include the smuggling or other unlawful importation of such articles into the United States.

FETRA provided for a Tobacco Transition Payment Program (TTPP) through which eligible former tobacco quota holders and tobacco producers received payments in 10 equal installments in each fiscal year 2005 through 2014. FETRA provided for the establishment of quarterly assessments on each domestic manufacturer and importer of tobacco products to fund the 10-year TTPP. The last assessment under FETRA was in September 2014, which encompassed the 39th and 40th quarterly TTPP assessments. The issuance of the 40th, or last, quarterly assessment, was on September 1, 2014, rather than on December 1, 2014, in accordance with statutory requirements specified in section 625(d)(3)(A) of FETRA. We are issuing this final rule consistent with section 919(b)(7) of the FD&C Act, which requires we ensure that we are able to make the determinations necessary for assessing tobacco product user fees.

II. Overview of the Final Rule

We are finalizing portions of the proposed rule with only minor changes. We amended § 1150.7(a)(1) and (2) to include language from the proposed rule specifying the calculations that FDA will perform to determine the yearly class allocation for cigars. Moreover, we added § 1150.9(a)(2) to codify the method by which FDA will calculate the percentage share for each domestic manufacturer and importer of cigars. In the proposed rule, we specifically discussed this proposed methodology, requested comment, and reserved § 1150.9(a)(2) for the purpose of including the calculations for manufacturers and importers in the cigar class if they became subject to chapter IX of the FD&C Act. After reviewing comments on the proposed rule, FDA is adding this methodology for cigars to § 1150.9(a)(2) without changes.

We added paragraph (c) to § 1150.5 to require that domestic manufacturers and importers of cigars report data for each prior month in the fiscal year in their first submission under this

rule. Once deemed, cigars and pipe tobacco will be subject to user fees under section 919 of the FD&C Act. However, domestic manufacturers and importers of cigars and pipe tobacco will start being assessed fees only at the start of the fiscal year following the effective date of this rule because we can only perform class allocations on a full fiscal year basis. As we discussed in section I.B. of the User Fee proposed rule (78 FR 32583), section 919(b)(5) of the FD&C Act requires FDA to allocate user fees within the cigar class to cigar firms based on the amount of excise taxes those firms paid in the prior fiscal year. This addition to § 1150.5 will ensure that FDA has data for the prior fiscal year necessary to calculate, assess, and collect user fees for domestic manufacturers and importers of cigars in the first fiscal year in which they are assessed fees. We do not need data for the full prior fiscal year from domestic manufacturers and importers of other tobacco products subject to user fees, including pipe tobacco, because percentage share calculations for those classes only requires prior fiscal quarter data.

We added paragraph (d) to § 1150.5 to require that domestic manufacturers and importers of pipe tobacco begin their monthly reporting of data in August 2016. As noted previously, FDA makes percentage share calculations for tobacco products other than cigars using prior fiscal quarter data. Because FDA will begin making percentage share calculations for domestic manufacturers and importers of pipe tobacco beginning in the first fiscal quarter of 2017, FDA does not need pipe tobacco firms to submit data for months prior to the fourth fiscal quarter of 2016. Requiring domestic manufacturers and importers of pipe tobacco to make their first submission of prior month data by August 20, 2016, ensures FDA will have data for each month of the fourth fiscal quarter in 2016 and will be able to complete percentage share calculations for pipe tobacco firms for the first fiscal quarter of 2017.

Further, in light of the Deeming rule subjecting cigars and pipe tobacco to user fee requirements, we added 21 U.S.C. 387a and 21 CFR 1100.1 to the authority section. Finally, we amended § 1150.5(a) by removing the phrases "that are part of a class of tobacco products that is subject to regulation under chapter IX of the Federal Food, Drug, and Cosmetic Act" and "beginning October 2014." We made these changes because all classes of tobacco products that are included in the definition of "class of tobacco products" are subject to chapter IX of the FD&C Act and it is no longer necessary to make such a distinction, and because the October 2014 compliance date has passed.

III. Comments on the Proposed Rule

We received 12 comments on the proposed rule. We addressed a majority of the comments in the User Fee final rule. We declined to address comments relating to cigars, pipe tobacco, and other deemed products in that document because they were outside of FDA's jurisdiction at the time. Now that the Deeming rule has expanded FDA's authority to cover those products, we address the comments on assessing user fees on tobacco products that FDA deemed subject to chapter IX of the FD&C Act in this section.

Comments were received from tobacco product manufacturers, trade associations, and individuals. To make it easier to identify comments and our responses, the word "Comment," in parentheses, will appear before each comment, and the word "Response," in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with the comment. We have combined similar comments under one numbered comment.

(Comment 1) Multiple comments addressed FDA's authority to assess and collect user fees from domestic manufacturers and importers of products that have been deemed subject to FDA's jurisdiction, particularly e-cigarettes. Some comments stated that FDA must assess and collect fees because no "free riders" are allowed under section 919(a) of the FD&C Act. These comments relied on the language in section 919(a) of the FD&C Act that FDA shall assess user fees on, and collect such from, each manufacturer and importer of tobacco products subject to chapter IX. The comments asserted that, unless deemed products are subject to user fees, "some regulated manufacturers and importers would have to pay the cost of their regulation plus the cost of regulating the non-paying manufacturers and importers," which would provide the non-paying manufacturers and importers a significant competitive advantage in terms of reduced costs and prices for their products. Several of the comments claimed that failure to assess user fees on deemed products would violate the Fifth Amendment. Some comments also contend that exempting some products from user fees is unfair to existing classes, arbitrary and capricious, and would violate the Administrative Procedure Act.

In contrast, other comments stated that FDA does not have the authority to assess user fees for any class other than the six classes named in section 919(b)(2)(B) of the FD&C Act and in FETRA. These comments noted that section 919(a) provides that fees must be assessed and collected "in accordance with this section" and, therefore, FDA can assess fees only on those classes identified in section 919 and FETRA. One of these comments also noted that the reallocation provision in section 919(b)(2)(B)(iv) permits reallocation only to regulated classes of the six FETRA classes. Similarly, another comment stated that FDA cannot deem electronic cigarette manufacturers to meet the definition of domestic manufacturer because FDA "is bound under the FD&C Act to follow the allocation procedures established under FETRA."

(Response) Section 919(b)(2) of the FD&C Act lists six classes of tobacco products for the purpose of allocating among the classes--cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. The comments raise the question of whether Congress intended FDA to assess fees for manufacturers and importers of tobacco products of only these six classes or intended that FDA create additional classes for other tobacco products and assess fees for them as well. In construing section 919 of the FD&C Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? ("Chevron step one"); Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (Young v. Community Nutrition Institute, 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the Agency must implement Congress' unambiguously expressed intent (Chevron, 467 U.S. at 842 to 843). If, however, section 919 is silent or ambiguous as to whether FDA must impose assessments on manufacturers and importers of only those classes of tobacco products listed in section 919(b)(2), FDA may determine whether section 919 should be interpreted to contain such a limitation, and FDA's interpretation must be upheld if it is reasonable ("Chevron step two"); Chevron, 467 U.S. at 842 to 843; FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000).

We have determined that, in enacting section 919 of the FD&C Act, Congress clearly manifested its intention that FDA only assess fees for manufacturers and importers of tobacco products in the six enumerated classes.

Section 919(a) of the FD&C Act states that FDA must assess fees "in accordance with this section," and section 919 provides a clear two-step process for assessing fees. The first step requires FDA to allocate fees to each class of tobacco products, which it does by multiplying the

total amount of fees per year by the "applicable percentage" for each class. Section 919(b)(2)(A) of the FD&C Act. Section 919(b)(2)(B) of the FD&C Act sets forth how to calculate these applicable percentages, but only for the six classes enumerated in section 919(b)(2). The applicable percentage is the percentage determined under section 625(c) of Pub. L. 108-357, which is FETRA. Section 919(b)(2)(B)(ii) of the FD&C Act. Section 625(c) of FETRA provides initial percentages for each of the six classes, totaling 100 percent, and mandates that subsequent allocations be made only among these same classes. See sections 625(c)(1) and (2) of FETRA. Because the percentage of the total user fee assessment for each class under section 919 of the FD&C Act is the FETRA percentage, the sum of the percentages for all six classes will always total 100 percent. Since the six classes must comprise 100 percent of the allocation of the total user fee assessment under section 919(b)(2) of the FD&C Act, adding a class of tobacco product beyond the six would increase the total to over 100 percent. This is a result that Congress could not have intended, because it would require FDA to assess and collect user fees beyond the total amount permitted by section 919(b)(1) of the FD&C Act. Moreover, even assuming that under section 919 of the FD&C Act the applicable percentage for a class could be something other than the FETRA percentage, nothing in section 919 sets forth how FDA must, or even could, determine that percentage. Thus, this first step shows that section 919 is limited to the six classes enumerated in section 919(b)(2) of the FD&C Act.

The second step in the process for assessing fees is to determine the share of fees for each manufacturer and importer within each class of tobacco products. Except for the cigar class, this percentage shall be the percentage determined for the purposes of allocations under subsections (e) through (h) of section 625 of FETRA. Section 919(b)(4) and (5) of the FD&C Act. This directive makes clear Congress' intent that all classes except cigars (as discussed in the next

paragraph) look to FETRA when calculating the percentage share of manufacturers and importers within a class. However, FETRA only yields, and by its text and structure can only yield, percentages for firms within the six listed classes. First, sections 625(e)(1) and (f) of FETRA provide allocations for each manufacturer and importer of tobacco products in each class "specified in subsection (c)(1)," which are the same six classes from section 919(b)(2) of the FD&C Act. Second, the FETRA allocations are based on each firm's share of the gross domestic volume for the class. Gross domestic volume is the volume of tobacco products "removed" and not exempt for Federal excise tax purposes. Section 625(a)(2) of FETRA. Thus, section 625(h) of FETRA sets forth the information required to be submitted to calculate the domestic volume of each manufacturer and importer, which relates to the removal of tobacco products for Federal excise tax purposes and the payment of such taxes. However, tobacco products outside the six classes listed in section 919 are not subject to Federal excise taxes, nor can such products be "removed" for Federal excise tax purposes. See 26 U.S.C. 52 and 26 U.S.C. 5702. Third, section 625(g) of FETRA provides measurement parameters to determine the volume of products removed, but they are explicitly limited to the six listed classes. The volume of domestic sales within a class are measured for the cigarette and cigar classes based on the number of cigarettes or cigars; for the remaining four classes specified in section 625(c)(1) of FETRA, they are measured based on the number of pounds. Because FETRA does not, and cannot, have allocations in the second step for products outside the six enumerated classes, it is clear that Congress intended only manufacturers and importers of tobacco products within those classes to be subject to user fees under section 919 of the FD&C Act.

This is reinforced by section 919(b)(5) of the FD&C Act, which sets forth a somewhat different process for calculating allocations among firms in the cigar class that is based on excise

taxes paid during the prior fiscal year rather than the prior quarter. That provision says that the allocation among firms in the cigar class is "notwithstanding" section 919(b)(4) of the FD&C Act, showing that Congress intended the modified process for cigars to be an exception to the rule of using the FETRA framework to determine each firm's share of the class assessment. Because section 919 of the FD&C Act does not provide any other exceptions, the FETRA percentages must be used for the allocations within all other classes.

Section 919(b)(7)(A) of the FD&C Act likewise limits the assessment of fees under section 919 to the six listed classes. This provision requires FDA to obtain, from the appropriate Federal Agency, all necessary information regarding all tobacco product manufacturers and importers required to pay user fees in order to make percentage calculations for each class (i.e., "applicable percentages of each class" under the statute, Section 919(b)(2)) and percentage share calculations within each class. As directed, FDA entered into a Memorandum of Understanding with the U.S. Department of Agriculture (USDA) to provide all the necessary information to FDA, and did so only for firms manufacturing or importing products in the six classes listed in section 919.[2] USDA could not provide "all necessary information" to FDA to make percentage share calculations for tobacco products in any other classes, nor could any other Federal Agency.

The reallocation provision in section 919 of the FD&C Act also shows that user fees cannot be imposed on products outside the six listed classes. This provision requires that the amount of user fees that would be otherwise be assessed to classes of tobacco products that are not subject to chapter IX of the FD&C Act must be reallocated to classes that are subject to chapter IX. Section 919(b)(2)(B)(iv) of the FD&C Act. This reallocation must be done in the

[2] USDA's authority to collect assessments under FETRA has sunset. Section 919(b)(7)(B) of the FD&C Act requires FDA to ensure that it is able to determine the applicable percentages described in section 919(b)(2) and the percentage shares described in section 919(b)(4). Thus, FDA issued a rule in July 2014, as well as this rule to require the submission of the necessary information to determine these percentages, which enables FDA to assess and collect the tobacco product user fees.

same manner and based on the same relative percentages otherwise determined under section 919(b)(2)(B)(ii). By its terms, section 919(b)(2)(B)(ii) of the FD&C Act can provide the applicable percentages for only the six classes in section 919(b)(2)(B)(i) because those percentages are determined under section 625(c) of FETRA. Accordingly, FDA is unable to reallocate any user fees to a class outside of the six. Thus, the only way that FDA could reallocate fees to classes that are subject to chapter IX of the FD&C Act is for the tobacco product classes to be limited to those listed in section 919(b)(2)(B)(i) of the FD&C Act and in FETRA. Any other interpretation would render the reallocation provision's express linkage to FETRA superfluous and contravene the clear intent of Congress.

Generally, comments that asserted that FDA should assess fees on all deemed tobacco products, including those outside the six classes, point to section 919(a) of the FD&C Act, which says that FDA shall assess user fees on, and collect such from, each manufacturer and importer of tobacco products subject to chapter IX. They argue that if electronic nicotine delivery systems (ENDS) and other tobacco products are deemed to be subject to chapter IX, then each manufacturer and importer of such products is subject to these fees. These comments, however, fail to take into account section 919(a)'s mandate that the assessment shall be done "in accordance with this section." As described previously, when the assessments are made in accordance with section 919's two-step process, they yield assessments only for tobacco products in the six classes.

Moreover, it is clear that, for the purposes of section 919 of the FD&C Act, including 919(a), the term "each manufacturer and importer of tobacco products" is limited to the tobacco products in the six classes. By its terms, Congress intended section 919 to work in accordance with the FETRA framework. Section 625 of FETRA, like section 919 of the FD&C Act, applies

to each "tobacco product manufacturer" and "tobacco product importer" and to each class of tobacco products. The terms manufacturer, importer, and tobacco product in section 919 of the FD&C Act and FETRA flow from the Internal Revenue Code (IRC). 26 U.S.C. 5702. Just as section 919 requires FDA to make the allocations--both for each class and within each class--based on FETRA, the FETRA allocations are based on removals for the purposes of Federal excise taxes. Thus, section 919 of the FD&C Act and FETRA, and their respective implementing regulations, use the same terms used in the IRC relating to Federal excise taxes. The classes of tobacco products are likewise consistent among the IRC, FETRA, and section 919 of the FD&C Act. The IRC defines six classes of tobacco products for Federal excise tax purposes.[3] The same six classes are enumerated in FETRA and section 919 of the FD&C Act for use in assessing the TTPP and tobacco user fees, respectively. Accordingly, in the IRC, FETRA, and section 919 of the FD&C Act, tobacco manufacturers are those who manufacture tobacco products in those six classes subject to Federal excise taxes. Any other approach to the term "each manufacturer and importer of tobacco products" in section 919 of the FD&C Act would lead to absurd results that Congress could not have intended. For example, section 900(20) of the FD&C Act defines "tobacco product manufacturer" as any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product. Relying on the section 900(20) definition would require FDA to assess user fees on each firm in the supply chain that, among other things, repacks, relabels, or distributes tobacco. However, doing so is impossible under the FETRA calculus mandated for the six classes under section 919 of the FD&C Act because FETRA calculates the relevant percentages based on the volume of product removed into domestic commerce (as defined by section 5702 of the IRC), and not tax

[3] The IRC definition of tobacco product includes five classes, including 'smokeless tobacco,' which is further defined to comprise two classes of tobacco products: Chewing tobacco and snuff. 21 U.S.C. 5702(c), (m).

exempt. Section 625(a)(2) and (3), (c)(2), (e) and (g) of FETRA. Some firms included in the section 900(20) of the FD&C Act definition of manufacturer, such as repackers and relabelers, do not "remove" products into domestic commerce as defined by the IRC because they are not removing products from a factory or bonded warehouse. Accordingly, these firms would not have a calculable volume of product removed into domestic commerce; as such, FDA could not calculate the user fees those firms would be assessed under section 919(b)(4) of the FD&C Act, nor could it determine how those firms affect class allocations under section 919(b)(2)(B) of the FD&C Act.

In contrast, using the definitions for manufacturer and importer in the IRC, and as adopted in USDA's and FDA's implementing regulations, allows FDA to make the necessary user fee allocations. This approach limits the entities to be assessed fees to those that must obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau (TTB) because they meet the definition of manufacturer of tobacco products or importer under the IRC and its implementing regulations (27 CFR 40.11 and 41.11). Only these entities are subject to Federal excise taxes under chapter 52 of the IRC and can "remove" tobacco products into domestic commerce. Thus, only these entities have a volume of domestic sales under FETRA and can be assessed user fees under section 919 of the FD&C Act.

Additionally, section 919 of the FD&C Act directly contradicts the section 900(20) definition in the manner it treats manufacturers and importers of tobacco products. Whereas the former treats manufacturers and importers as distinct entities for the purpose of assessments and collections, the section 900(20) definition includes importer as a subset of manufacturer, since the latter includes any person who imports a finished tobacco product for sale or distribution in

the United States. Thus, Congress did not intend FDA to use the section 900(20) definition for the purposes of section 919.

Likewise, Congress could not have intended section 919 of the FD&C Act to incorporate the definition of "tobacco product" in section 201(rr) (21 U.S.C. 321(rr)) or the tobacco product definitions from section 900 of the FD&C Act. The former includes any "component, part, or accessory" of a tobacco product, which is significantly broader than the definitions for the different types of tobacco products in the IRC and FETRA. Similarly, the definition of "cigarette" in section 900(3) of the FD&C Act includes roll-your-own tobacco for cigarettes. If FDA calculated user fee assessments relying the definitions of "cigarette" and "roll-your-own" found in section 900(3) and 900(15) of the FD&C Act, respectively, manufacturers and importers of roll-your-own cigarettes would be required to pay fees both as part of the cigarette class and as part of the roll-your-own class. Such duplicative assessments would run contrary to section 919(b)(3)(B) of the FD&C Act, which expressly precludes manufacturers and importers from paying a user fee in excess of their percentage share. To prevent this, tobacco product classes must be distinct, and cannot overlap. Using the tobacco product definitions found in section 5702 of the IRC avoids double-billing firms because the classes are structured such that they are distinct and non-overlapping. Thus, for the term "each manufacturer and importer of tobacco products," Congress intended FDA to use the term in the IRC and FETRA.

While the definitions in sections 201(rr) and 900 of the FD&C Act say they apply for the purposes of the FD&C Act and chapter IX of the FD&C Act, respectively, this cannot be the case when doing so would run counter to the statutory purpose of a particular provision. Although there may be "a natural presumption that identical words used in different parts of the same act are intended to have the same meaning [citation omitted]…the presumption is not

rigid…." (Atlantic Cleaners & Dryers, Inc. v. U.S., 286 U.S. 427, 433 (1932); (accord: Yates v. U.S., 135 S. Ct. 1074, 1082 (2015)). Thus, the same words may be given different meanings, even in the same statute, if Congress intended different interpretations (at Chevron step one) or if such different interpretations are reasonable (at Chevron step two) (Atlantic Cleaners & Dryers, Inc., supra). See also Lawson v. Suwannee S.S. Co., 336 U.S. 198, 201 (1949); Nw. Austin Mun. Util. Dist. No. One v. Holder, 557 U.S. 193, 205 to 206 (2009). For the reasons given, it is clear that Congress intended the terms in section 919 to be consistent with the counterpart terms in FETRA and the IRC.

Nothing in the legislative history of section 919 of the FD&C Act undermines this view that user fees are limited to the six enumerated classes. To the contrary, this interpretation is reinforced by the legislative history of the Tobacco Control Act, which states that the method of assessing fees shall be the same as that currently used by United States Department of Agriculture for all tobacco manufacturers and importers to fund the 2004 legislation providing transitional payments to tobacco grower quota holders. H. Rpt. 111-58, p. 47. Because products other than those in the six listed classes are not "removed" and are not subject to a Federal excise tax, a user fee methodology for them could not be the same as that used by USDA under FETRA.

Having concluded that the statutory scheme precludes FDA from assessing user fees on classes of tobacco products beyond the six listed in section 919 of the FD&C Act, the Chevron analysis need not proceed further. However, in the alternative, even if section 919 of the FD&C Act is ambiguous as to whether classes beyond the six may be subject to user fee assessments, FDA would adopt the same interpretation of the statute in an exercise of its discretion. In conducting this Chevron step two analysis, the Agency has based its conclusion on the same

considerations discussed previously as well as the considerations discussed later in this document (Bell Atlantic Telephone Co. v. FCC, 131 F.3d 1044, 1049 (D.C. Cir. 1997); Chevron U.S.A., Inc. v. FERC, 193 F. Supp. 2d 54, 68 (D.D.C. 2002)). FDA's interpretation of section 919 of the FD&C Act as assessing user fees only on the six classes of tobacco products listed in section 919(b)(2)(B)(ii) of the FD&C Act is reasonable. (Chevron, USA, Inc. v. NRDC, Inc., supra at 843).

FDA's interpretation is consistent with the text and statutory structure of section 919. The statute requires FDA to use the FETRA percentages, and thus the FETRA formula, to determine the applicable percentages of the six classes listed in section 919(b)(2)(B)(i) of the FD&C Act, but it gives no indication of the manner under which FDA could or should determine user fee allocations for any additional classes. By using the FETRA framework, the applicable percentages for the six classes listed in section 919(b)(2)(B)(ii) are determined by a basic and predictable calculation. In addition, the user fee calculation is based on the share of gross domestic volume, which is inextricably linked to the volume of tobacco products removed that are subject to Federal excise taxes--information that was readily available to FDA at the time the Tobacco Control Act was enacted. For these six classes, Congress thus provided an easy-to-implement system that gives FDA relatively little discretion in determining the assessments.

As discussed previously, the class percentage for classes beyond the six cannot be determined pursuant to the FETRA framework since those classes do not have volumes as defined in section 625(a) of FETRA. Thus, in order to assess any user fees on any class of tobacco products beyond the six listed in section 919 of the FD&C Act, FDA would need to demarcate a new set of tobacco product classes among newly deemed tobacco products, and fashion an entirely novel framework for determining class percentage allocations and allocations

within each class of tobacco product. It would have to do this against the backdrop of the range of tobacco products, including various types of ENDS (such as e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes), as well as nicotine gels, nicotine toothpicks, etc.

Even if section 919 of the FD&C Act somehow allowed FDA to allocate percentages to and among additional classes, nothing in section 919 sets forth the methodology FDA must, or even could, use to calculate these percentages or how FDA would obtain the necessary information for doing so. Since 100 percent of the total amount of user fees to be assessed are allocated among the six classes listed in section 919(b)(2)(B)(ii) of the FD&C Act, FDA would need to devise a common metric for comparing each of these novel tobacco product classes to those six listed in order to adjust the relative class percentages (and find authority under section 919 to make such adjustments). FDA could not use the common metric adopted by USDA and, subsequently, by FDA in its 2014 final rule. This is based on the 2003 maximum Federal excise tax rates, which do not exist for tobacco products beyond the six classes. Further, because section 919(b)(2)(B)(ii) of the FD&C Act states that the applicable percentages for the six listed classes are the percentages from FETRA, for FDA to adjust those percentages based on a novel common metric external to FETRA would violate the statutory terms of that section.

Some commenters argued that FDA could and should abandon the tax-based methodology from FETRA altogether and create an entirely novel system unrelated to taxes or tax rates for determining the applicable percentages for both new and existing tobacco product classes. However, this suggestion also falters against the plain language of section 919(b)(2)(B)(ii) of the FD&C Act, which requires FDA to use the FETRA percentages for the six listed classes; deviating from FETRA's methodology for allocations would contradict the

clear intent of Congress. Moreover, it is reasonable to conclude that Congress did not intend FDA to develop a new system that departs from the methodology mandated by FETRA. Any such system would necessarily be subjective, especially relative to the system Congress established for the enumerated six classes. As such, FDA's interpretation is a reasonable construction of the FD&C Act.

We disagree with commenters that a failure to assess fees on all deemed tobacco products is arbitrary and capricious. FDA is implementing the system established by Congress, which does not allow FDA to assess user fees for products outside the six classes. Even assuming section 919 of the FD&C Act is ambiguous regarding this point, for the reasons previously stated, FDA's interpretation here is reasonable. We also disagree with comments that argued that FDA's proposed scheme amounts to a tax because there is no tangible benefit to manufacturers and importers required to make user fee payments vis-à-vis those that are not, as required under the Independent Offices Appropriations Act (IOAA). Because Congress granted FDA independent statutory authority to assess user fees, the requirements of the IOAA do not apply. See American Medical Ass'n v. Reno, 857 F. Supp. 80, 84 (D.D.C. 1994); National Cable Television Ass'n, Inc. v. United States, 415 U.S. 336 (1974). Finally, we do not need to address commenters' Fifth Amendment arguments here because the FD&C Act itself differentiates between the six classes listed in section 919(b)(2)(B)(ii) and other tobacco product classes. As explained, FDA is merely following Congress' intent as expressed in section 919 of the FD&C Act.

(Comment 2) One comment stated that FDA should formulate a reasonable common metric to assess user fees on all regulated tobacco products, including those not subject to excise taxes. This comment said that a common metric was needed to compare new classes of tobacco

products with existing classes and suggested that FDA "could base its calculations on total sales (in units) of each tobacco product, using traditional selling-sizes or weights of packages (e.g., 20 cigarettes = 1 e-cigarette cartridge = 1 standard container of moist snuff = 4 large cigars) to derive the conversion factor necessary for market share calculations." Another comment stated that FDA should develop a method for calculating user fees for deemed products, not within the six classes, before any deeming regulation takes effect.

(Response) FDA disagrees with these comments. As discussed in the response to comment 1, section 919 of the FD&C Act prevents FDA from assessing and collecting user fees from manufacturers and importers of deemed products other than cigars and pipe tobacco. Creating a common metric among all product classes subject to FDA regulation would not change the requirements of section 919 of the FD&C Act that prevent FDA from assessing user fees for deemed products other than cigars and pipe tobacco.

(Comment 3) One comment stated that FDA should not adopt the USDA's retrospective calculation method for determining class percentage allocations at Step A because of concerns that a regulation deeming additional products subject to FDA regulation could dramatically alter class allocations from year to year, and that class allocation calculations using this method will not be an accurate reflection of each class' current percentage allocation. This comment stated that small businesses may no longer be able to sell deemed products withdrawn from the market due to premarket authorization requirements, but may still have to pay their share of their respective classes' user fees. Other companies that market grandfathered deemed products, the comment argued, would be forced to pay a disproportionate share based upon a class determination that was calculated before the deeming regulation. The comment requested that FDA include safeguards against inequitable retrospective user fee requirements or allow for the

continued marketing of deemed products while their corresponding premarket applications are pending review.

(Response) FDA disagrees with this comment. FDA is unable to alter the user fee calculations required by section 919 of the FD&C Act. In determining the user fees to be assessed on each class of tobacco products, section 919(b)(2)(B)(ii) of the FD&C Act provides that the applicable percentage for each tobacco product class shall be the percentage determined under section 625(c) of FETRA for each such class of product for such fiscal year. Relying on the initial allocation percentages in section 625(c) of FETRA, USDA calculated the yearly class allocations for each fiscal year based on data about removals covering the most recent full calendar year (see 70 FR 7007). As such, FDA's class allocations are calculated in the same manner. Section 919 also requires FDA to calculate assessments on each manufacturer and importer within a class on a quarterly basis using the prior quarter's tax removal data for products other than cigars and the prior fiscal year's tax removal data for cigars. While it is true that class allocations between product classes and percentage shares between companies within product classes can fluctuate throughout the year, FDA cannot alter the required method of user fee calculations.

(Comment 4) One comment argued that premium cigars should be exempt from FDA regulation generally and user fees specifically because FDA regulation would be disproportionately burdensome for the product segment, as exemplified by the new product (or premarket) requirements that would be triggered by the often minor ingredient variations intended to alter the taste and aroma of a premium cigar.

(Response) FDA disagrees with this comment. In the Deeming rule, FDA concluded that all cigars should be deemed subject to chapter IX of the FD&C Act and, in doing so, took into

account the concerns about premarket authorization requirements raised in this comment. All cigars have been deemed subject to FDA's regulation and, as such, are subject to user fees under section 919 of the FD&C Act. Furthermore, FDA lacks the authority to exempt any portion of a class that has been deemed subject to chapter IX of the FD&C Act from user fee requirements.

(Comment 5) FDA received comments addressing the calculation of user fee assessments for domestic manufacturers and importers of cigars. One commenter asserted that using the amount of excise tax paid to determine percentage share within the cigar class would favor importers over domestic manufacturers because importers "can typically sell cigars to distributors at a lower price" because they benefit from lower wages, taxes, and regulatory costs. The commenter stated that actual units (sticks) would better reflect true market share and using excise taxes paid to calculate percentage share would increase incentives to move production and jobs off-shore.

Another comment suggested that FDA consider the differences in taxation of cigars compared with other taxable classes of tobacco products and assess the rule's "potentially inequitable impact on cigar manufacturers and importers." The comment asserted that the different excise tax rates applied within the cigar class would have the "unintended consequence" of causing manufacturers and importers of similar products to pay dramatically different amounts in user fees. The commenter further stated that large cigars have different first wholesale prices, and that some of these pricing differences are due to economies of scale or other efficiency factors. Companies with significant economies of scale would benefit by paying lower user fees due to their products being produced at lower cost, while small manufacturers and importers would be disadvantaged.

(Response) FDA disagrees with the suggestion that it can use something other than excise taxes to calculate the percentage share of manufacturers and importers in the cigar class. Section 919(b)(5) of the FD&C Act specifies that "if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year." We acknowledge that this method of calculating cigar manufacturers' and importers' percentage share depends on the excise tax rate and would result in manufacturers and importers of small cigars paying a lower dollar amount of user fees per stick than manufacturers and importers of large cigars because large cigars are taxed at a higher rate than small cigars. However, we disagree that this would favor importers over domestic manufacturers and that it would encourage manufacturers to move abroad. Low volume, higher priced cigars are both more expensive and largely manufactured abroad. Importers of the higher priced cigars would pay more in user fees under the FD&C Act methodology than under a system in which volume was determined based on sticks.

In addition, we disagree that differences in user fee assessments across cigar types would be an unintended consequence of the FD&C Act methodology and that it would be inequitable. Cigars are a heterogeneous group of products, differing in such attributes as size and quality. The market for cigars is sufficiently competitive that price differences primarily reflect these product differences. It is not inequitable for products that differ greatly, as measured by market price, to pay different amounts of user fees. Moreover, the statute expressly states that each cigar manufacturer's or importer's percentage share must be calculated based on excise taxes paid. Congress thus clearly intended that user fees for cigars would vary depending on the excise taxes imposed on cigars, which in turn vary depending on the price and size of cigars.

IV. Legal Authority

Section 901 of the FD&C Act provides that chapter IX of the FD&C Act applies to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to this chapter. In accordance with section 901, FDA is issuing the Deeming rule (published elsewhere in this issue of the Federal Register) to extend FDA's "tobacco product" authorities to products that meet the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act, except the accessories of these tobacco products. Section 919(b)(7) of the FD&C Act requires that FDA ensure we are able to determine the applicable percentages described in section 919(b)(2) and the percentage shares described in section 919(b)(4). Section 909(a) of the FD&C Act authorizes FDA to issue regulations requiring tobacco product manufacturers or importers to 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(4), a tobacco product is deemed to be adulterated if the manufacturer or importer of the tobacco product fails to pay a user fee assessed to it under section 919 of the FD&C Act. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act. Consistent with these authorities, FDA is issuing this rule, which is intended to ensure that we are able to make the determinations required by section 919 of the FD&C Act and assess and collect tobacco product user fees.

V. Environmental Impact

The Agency has 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.

VI. Economic Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601 to 612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies 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). FDA has determined that this final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The potential impact on small entities is uncertain, and FDA is unable to rule out the possibility that this final rule may have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies 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 $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Under our baseline, FDA would obtain the information necessary for collecting cigar and pipe tobacco user fees directly from other Federal Agencies that collect such information.

Compared with this baseline, this final rule would impose both initial transition costs and monthly information submission costs on industry. There would also be an approximately offsetting reduction in government information collection costs. The net effect of this may be a small social cost or benefit. This final rule would also allow FDA to have full access to the data needed for calculating and billing user fees and would resolve impediments that may otherwise exist concerning FDA's ability to use the data for its intended purpose. This final rule can be expected to eliminate the potential need for additional regulatory mechanisms to collect information and allow user fee assessment to proceed more smoothly than it could otherwise.

Compared to the baseline, the estimated one-time private sector transition cost is $159.36 per manufacturer or importer, including small manufacturers and importers, and the annual compliance cost is $2,549.76. One option for regulatory relief would be to exempt firms from reporting in a particular month if they did not introduce any units of any tobacco products for which user fees are assessed into domestic commerce. Another option for regulatory relief would be to require submission of either the FDA form or copies of forms submitted to other Agencies. The full analysis of economic impacts is available as Ref. 1 in Docket No. FDA-2012-N-0920 and at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

VII. 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 (the PRA) (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting 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: Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco.

Description: This final rule requires each domestic manufacturer and importer of cigars and pipe tobacco to submit to FDA information needed to calculate and assess user fees under the FD&C Act.

The USDA collected information to calculate percentage share for its purposes and provided FDA with the data FDA needs to determine user fee assessments under the FD&C Act. USDA ceased collecting this information at the end of fiscal year 2014. Consistent with the requirements of the FD&C Act, this rule continues the submission of this information, but to FDA rather than USDA, and thus ensures that FDA continues to have the information needed to calculate the amount of user fees assessed to each entity and collect those fees. Section 919 of the FD&C Act establishes the user fee allocation and collection process, which references the FETRA framework for determining tobacco product class allocations and individual domestic manufacturer or importer allocations. As was required by USDA under FETRA, the final rule requires domestic manufacturers and importers of tobacco products to submit to FDA each month a form with summary information and copies of the reports or forms that relate to the tobacco products removed into domestic commerce.

Description of Respondents: Domestic manufacturers and importers of newly deemed tobacco products.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA. The requirements were approved and assigned OMB control number 0910-0749. This approval expires on July 31, 2017.

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.

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
1150.5(a), (b)(1), (b)(2), and FDA Form 3852 (Ref. 2) General identifying information provided by manufacturers and importers of FDA regulated tobacco products and Identification and removal information (monthly)	135	12	1,620	3	4,860
1150.5(b)(3) Certified Copies (monthly)	135	12	1,620	1	1,620
1150.13 Submission of user fee information (Identifying information, fee amount, etc. (quarterly)	68[2]	4	272	1	272
1150.15(a) Submission of user fee dispute (annually)	1	1	1	10	10
1150.15(d) Submission of request for further review of dispute of user fee (annually)	1	1	1	10	10
Total					6,772

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This figure was rounded to the nearest tenth.

Table 1 describes the annual reporting burden of 6,772 hours as a result of the provisions set forth in this proposed rule. Our estimated number of 135 newly deemed respondents (335 total tobacco entities) is based on 2013 summary information obtained from the Alcohol and Tobacco Tax and Trade Bureau (TTB) regarding the number of permitted manufacturers and importers. As referenced previously, the PRA burden for currently regulated products was previously approved by OMB. The burden analysis for that collection assumed 200 respondents

would submit user fees. Therefore given our updated estimate of 335 entities, the total number of new deemed tobacco entities is 135 (335 - 200 = 135). FDA estimates that there are 113 cigar manufacturers and 74 pipe tobacco manufacturers, as well as 216 importers of cigars and 43 importers of pipe tobacco. However, these estimates from TTB reflect that in 2013 there were 135 total permitted manufacturers and 200 permitted importers over all tobacco product types for which TTB collects excise taxes (including cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-you-own tobacco, excluding electronic nicotine delivery systems). This total is less than the sum across all tobacco product types because some manufacturers and importers produce or import more than one type of tobacco product (we subsequently refer to these entities as polymanufacturers and polyimporters). As the number of cigar and pipe tobacco manufacturers cannot exceed the number of permitted entities, we use 335 as an upper bound estimate of the number of affected entities. The estimate of 135 respondents reflects both reports of no removal into domestic commerce and reports of removal of tobacco product into domestic commerce. The estimate of 68 respondents reflects an average number of domestic manufacturers and importers who may be subject to fees each fiscal quarter. FDA assumes half the number of respondents will submit quarterly payments to the Agency. Based on our experience with the assessment of user fees for other FDA-regulated products, we estimate that approximately one respondent might appeal an assessment, and one respondent will request for further review of their dispute.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that would 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, the Agency has concluded 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.

IX. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Regulatory Impact Analysis. Available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

2. Form FDA 3852.

List of Subjects in 21 CFR Part 1150

Tobacco products, User fees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1150 is amended to read as follows:

PART 1150--USER FEES

1. The authority citation for part 1150 is revised to read as follows:

Authority: 21 U.S.C. 371, 387a, 387b, 387i, 387s, 21 CFR 1100.1.

2. In § 1150.3, revise the definition for “Units of product” to read as follows:

§ 1150.3 Definitions.

* * * * *

Units of product means:

(1) The number of sticks for cigarettes and cigars, or

(2) The weight (measured in pounds) for snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

* * * * *

§ 1150.5 [Amended]

3. Amend § 1150.5 by:

a. Removing from the first sentence of paragraph (a) the phrases "that is subject to regulation under chapter IX of the Federal Food, Drug, and Cosmetic Act" and "beginning October 2014".

b. Adding paragraphs (c) and (d) to read as follows:

§ 1150.5 Required Information.

* * * * *

(c) First report for cigars. Domestic manufacturers and importers of cigars must submit the information described in this section beginning no later than the 20th day of August, 2016. Domestic manufacturers and importers of cigars must submit the information described in this section for each of the prior months of fiscal year 2016 as their first monthly submission. The previous sentence only applies for the first report in fiscal year 2016.

(d) First report for pipe tobacco. Domestic manufacturers and importers of pipe tobacco must submit the information described in this section beginning no later than the 20th day of August, 2016.

* * * * *

5. In § 1150.7, revise paragraph (a)(1) and add paragraph (a)(2) to read as follows:

§ 1150.7 Yearly class allocation.

* * * * *

(a) * * *

(1) Except for cigars, FDA will multiply the units of product removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for that class (class dollar figure).

(2) For cigars, FDA will:

(i) Multiply the units of small cigars removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for small cigars (small cigar subclass dollar figure).

(ii) Multiply the units of large cigars removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for large cigars (large cigar subclass dollar figure).

(iii) Add the small cigar subclass dollar figure and the large cigar subclass dollar figure (cigar class dollar figure).

* * * * *

6. In § 1150.9, revise paragraph (a)(1) and add paragraph (a)(2) to read as follows:

§ 1150.9 Domestic manufacturer or importer assessment.

* * * * *

(a) * * *

(1) For each class of tobacco products except cigars, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior quarter by the total excise taxes that all domestic manufacturers and importers paid for the class for that same quarter.

(2) For the cigar class, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior fiscal year by the total excise taxes that all domestic manufacturers and importers paid for the class for the prior fiscal year.

* * * * *

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-10688 Filed: 5/5/2016 8:45 am; Publication Date: 5/10/2016]