(g) Retained Inspections: Group 1 Airplanes

This paragraph restates the actions required by paragraph (g) of AD 2014–03–06, Amendment 39–17743 (79 FR 12368, March 5, 2014) with no changes. For airplanes identified in Group 1 of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013: At the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013, except as required by paragraph (i) of this AD, do inspections and applicable corrective actions using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(h) Retained Inspections: Groups 2–7 Airplanes

This paragraph restates the actions required by the introductory text of paragraph (h) of AD 2014–03–06, Amendment 39–17743 (79 FR 12368, March 5, 2014) with no changes. For airplanes identified in Groups 2 through 7 of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013: At the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013, except as required by paragraph (i) of this AD, do high frequency eddy current inspections to detect cracking of the aft support fitting for the MLG beam, and the rear spar upper chord and rear spar web in the area of rear spar station 224.14, as applicable, in accordance with Option 1, 2, or 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013.

(1) This paragraph restates the actions required by paragraph (h)(1) of AD 2014–03–06, Amendment 39–17743 (79 FR 12368, March 5, 2014) with no changes. If no crack is found, repeat the inspection thereafter at the time specified in paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013, as applicable. Accomplishment of the inspection of the 12 fastener holes (locations 1–12) in accordance with Option 2, Action 3; or Option 3, Action 3; as specified in note (b) of tables 2 through 5 of paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013; terminates only the corresponding inspections that include note (b) in the ''Repeat Interval'' column of the applicable table.

(2) This paragraph restates the actions required by paragraph (h)(2) of AD 2014–03–06, Amendment 39–17743 (79 FR 12368, March 5, 2014), with revised paragraph references to the introductory text of paragraph (h) and to paragraph (h)(1) of this AD to mandate corrective actions. If any crack is found during any inspection required by the introductory text of paragraph (h) or by paragraph (h)(1) of this AD, repair before further flight using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Retained Exception to Service Information Specifications

This paragraph restates the actions required by paragraph (i) of AD 2014–03–06, Amendment 39–17743 (79 FR 12368, March 5, 2014), with no changes. Where Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013, specifies a compliance time ''after the original issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after April 9, 2014 (the effective date of AD 2014–03–06).

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA), which has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2014–03–06, Amendment 39–17743 (79 FR 12368, March 5, 2014), are approved as AMOCs for the corresponding provisions of this AD.

(k) Related Information

For more information about this AD, contact Nancy Marsh, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6440; fax: 425–917–6590; email: *nancy.marsh@faa.gov*.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on April 9, 2014 (79 FR 12368, March 5, 2014).

(i) Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013.

(ii) Reserved.

(4) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com*.

(5) You may view this service information at FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Renton, Washington on June 6, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–14475 Filed 7–9–14; 8:45 am]

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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

Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

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 tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The United States Department of Agriculture (USDA) has been collecting this information and providing FDA with the data FDA needs to calculate the amount of user fees assessed to tobacco product manufacturers and importers. USDA intends to cease collecting this information starting in fiscal year 2015 (October 2014). Consistent with the requirements of the FD&C Act, the final rule requires the submission of this information to FDA instead of USDA.

DATES: This rule is effective August 11, 2014.

FOR FURTHER INFORMATION CONTACT: Nancy Boocker or Annette Marthaler,

Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002; 1–877–287–1373, *CTPRegulations@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Final Rule

The final rule will provide FDA with the information it needs to calculate the amount of user fees assessed for each domestic 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. That total is divided into four equal quarterly assessments. The FD&C Act provides for the total quarterly assessment to be allocated among classes of tobacco products and then, within each class of tobacco products, among individual domestic manufacturers and importers. 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.)), which is administered by USDA. To date, FDA has received the information needed to calculate user fees from USDA. When the USDA program sunsets at the end of fiscal year 2014 (September 30, 2014), FDA, as required by the FD&C Act, will need to provide for an alternative source of the information necessary to calculate user fees.

Legal Authority

This rule is being issued based upon FDA's authority to calculate, assess, and collect tobacco product user fees pursuant to section 919 of the FD&C Act as well as FDA's rulemaking authority under sections 909(a) and 701(a).

Summary of the Major Provisions

The final rule applies to domestic manufacturers and importers of four classes of tobacco products: Cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. Beginning October 2014, the rule requires each domestic manufacturer or importer of these four product classes to submit to FDA specific information regarding units of product removed [1] into domestic commerce and Federal excise taxes paid for each class of tobacco product. The information must be submitted on a monthly basis, even in months when no tobacco product is removed into domestic commerce. This final rule specifies that FDA will continue to follow the current method for allocating the total fees among classes of tobacco product. We will calculate the appropriate allocation by multiplying the total units removed (sticks or pounds) for the class by the 2003 maximum excise tax rate for that class and then calculating each class' percentage of the total quarterly assessment. The final rule also specifies that FDA will continue to use the current method of assessing user fees within each tobacco product class—by multiplying the total amount assessed to the class times the percentage share of Federal excise taxes paid by each domestic manufacturer and importer using information required to be provided to FDA under this final rule. If additional classes of tobacco products are deemed subject to FDA's tobacco regulation, FDA will conduct a new rulemaking to subject those classes to this user fee rule. In addition, the final rule includes provisions about notification of assessments, payment of assessments, procedures for disputing an assessment, and penalties for failure to report required information to FDA or failure to pay tobacco product user fees.

Costs and Benefits

Under our primary baseline, starting in fiscal year 2015, FDA would obtain the information necessary for collecting user fees directly from Federal Agencies (other than USDA) that collect such information. Compared with this baseline, the final rule will impose private costs on industry to submit data to FDA on a monthly basis, with an approximately offsetting reduction in government information collection costs. The net effect may be a small social cost or benefit. This final rule also allows FDA to be in control of the data needed for calculating and billing user fees and resolves impediments that may otherwise exist to FDA's ability to use the data for its intended purpose.

Table of Contents

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 new chapter IX (sections 900–920 (21 U.S.C. 387–387u)). 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 (section 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 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.[2] More specifically, the Tobacco Control Act gives FDA the authority to, among other things:

- Restrict cigarettes and smokeless tobacco 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

[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.''

[2] On April 25, 2014, FDA published a notice of proposed rulemaking to propose that additional tobacco products be deemed subject to chapter IX of the FD&C Act (79 FR 23142).

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
- in accordance with section 919, assess and collect user fees from each domestic manufacturer and importer of tobacco products subject to the tobacco product provisions 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 (NPRM) to add 21 CFR part 1150 to require domestic tobacco product manufacturers and importers to submit to FDA information needed to calculate the amount of user fees assessed under the FD&C Act. This final rule requires domestic tobacco product manufacturers and importers to submit that information beginning October 2014.

The final rule is issued under section 919(a) of the FD&C Act, which requires FDA, in accordance with that section, to ''assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products'' subject to the tobacco product provisions of 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 classes of tobacco products. The class allocation is based on each tobacco product class' volume of tobacco products removed into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its market 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, Public Law 108–357 (7 U.S.C. 518 et seq.)). 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.'' In determining the user fee to be paid by each company, section 919(b)(4) of the FD&C Act directs that we use percentage share information ''determined for purposes of allocations under subsections (e) through (h) of section 625 of [FETRA].''

FETRA provides for a Tobacco Transition Payment Program (TTPP), administered by the USDA, through which eligible former tobacco quota holders and tobacco producers receive payments in 10 equal installments in each fiscal year 2005 through 2014. FETRA provides 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 will be in September 2014, which will encompass the 39th and 40th quarterly TTPP assessments. The issuance of the 40th, or last, quarterly assessment will be on September 1, 2014, rather than on December 1, 2014, in accordance with statutory requirements specified in section 625(d)(3)(A) of FETRA (see 78 FR 46905, August 2, 2013). Because section 919 refers to FETRA information and calculations that are currently being made by USDA, FDA has been relying on USDA information for its tobacco product user fee calculations. In light of the sunset of the TTPP program, we are issuing this final rule consistent with section 919(b)(7) of the FD&C Act, which requires that no later than fiscal year 2015, we ensure we are able to make the determinations necessary for assessing tobacco product user fees.

Both USDA's TTPP program and FDA's user fee program follow a two-step process to calculate quarterly assessments:

- Step A allocates assessments among the six classes of tobacco products statutorily identified in those programs—cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco—based on each class' volume of tobacco products removed into commerce (section 625(c) of FETRA; 7 CFR 1463.4, 1463.5; and section 919(b)(2)(B) of the FD&C Act). To make this allocation, we will use the same approach and publicly available TTB data that is currently used by USDA (see 78 FR 32581 at 32585 and 32586; 70 FR 7007 at 7007 and 7008, February 10, 2005). The volume of tobacco products removed into domestic commerce for each class is multiplied by the maximum 2003 Federal excise tax rate for that class to generate a dollar figure for the class of tobacco products. The dollar figures for each of the six classes of tobacco products are added, and this aggregate dollar figure is the denominator. The dollar figure for each class of tobacco products is the numerator, and when divided by the aggregate dollar figure, the resulting quotient is the percentage attributable to the class. By using a fixed excise tax rate as a conversion factor, this calculation bases changes in user fee assessments solely on changes in volume of tobacco products removed. As discussed in the NPRM, cigars and pipe tobacco are two classes of products that are not currently regulated under chapter IX of the FD&C Act; as such, they are not currently assessed user fees by FDA. Section 919 provides that the allocation of fees that otherwise would be assessed to unregulated classes of tobacco products are to be reallocated to the classes of tobacco products currently subject to chapter IX of the FD&C Act. Therefore, the total dollar amount of allocations that would be assessed for cigars and pipe tobacco is reallocated, based on relative percentages already calculated, to the four classes of currently regulated tobacco products: Cigarettes, snuff, chewing tobacco, and roll-your-own tobacco.
- Step B allocates the assessment for each class of tobacco products among the domestic manufacturers and importers in that class, so that each domestic manufacturer's or importer's assessment is proportional to its percentage share within that class (section 625(e) through (h) of FETRA; 7

CFR 1463.7; and section 919(b)(3) through (b)(5) of the FD&C Act).

II. Overview of the Final Rule

We considered all of the comments to the NPRM. We are finalizing portions of the proposed rule with only minor changes. In response to the comments, we have revised § 1150.15, regarding disputes, to clarify how initial disputes concerning fees and any subsequent requests for further Agency review are to be submitted, the date on which they are due, and that domestic manufacturers and importers are eligible to dispute an assessment. We also clarify that a dispute and any subsequent request for further review must be legible and in English. Although not raised by comments, we have also made minor clarifying edits to §§ 1150.3, 1150.5 and 1150.7. We have also revised § 1150.7(a)(1) to recognize that cigarettes are divided into subclasses for excise tax purposes (small and large cigarettes) and to clarify that our Step A calculations will use the maximum 2003 excise tax rate for small cigarettes for that subclass, rather than using the maximum 2003 excise tax rate (i.e., the excise tax rate for large cigarettes) for all cigarettes. This revision applies only for cigarettes because there are separate excise tax subclasses for cigarettes, and, therefore does not apply to chewing tobacco, roll-your-own tobacco, or snuff. We are not finalizing the portions of the proposed rule relating to the assessment of fees on cigars and pipe tobacco. As described more fully in section III.A of this document, we will revise our user fee regulations in the future if FDA deems cigars or pipe tobacco subject to FDA's authority under chapter IX of the FD&C Act. In addition, as discussed in section III.A, we may revise our user fee regulations if FDA deems additional tobacco products, other than cigars and pipe tobacco, subject to FDA's authority.

III. Comments on the Proposed Rule

We received 12 comments on the proposed rule. 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 them. We have combined similar comments under one numbered comment. In addition to the comments specific to this rulemaking that we address in the following paragraphs, we received two general comments: One expressing a view that all cigarettes should be prohibited, and one expressing a view that too much attention has been focused on the regulation of tobacco products. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response.

A. Tobacco Products Not Currently Subject to FDA Regulation

(Comment 1) Multiple comments addressed FDA's authority to assess and collect user fees from domestic manufacturers and importers of products that, in the future, may be deemed subject to FDA's jurisdiction, particularly electronic 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 fees 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 nonpaying manufacturers and importers,'' which would provide the nonpaying 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 contended that exempting some products from user fees would be unfair to existing classes, arbitrary and capricious, and violate the Administrative Procedure Act (5 U.S.C. Subchapter II).

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, that 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.''

Other comments focused on the burden of regulation more generally to say that their products should be exempt from user fee assessments. One comment argued that premium cigars should be exempt from FDA regulation generally and user fees specifically because FDA regulation would be disproportionately burdensome, as exemplified by the new product requirements in section 910 of the FD&C Act, which would be triggered by the often minor variations intended to alter the taste and aroma of a premium cigar.

(Response) Because these comments are related to tobacco products that are not currently subject to FDA's regulation under chapter IX of the FD&C Act, we do not need to address them at this time. This final rule applies to only domestic manufacturers and importers of the classes of tobacco products identified in section 919 that are currently subject to FDA's regulation under chapter IX of the FD&C Act.

We are not finalizing the portions of the proposed rule relating to the assessment of fees on the cigar and pipe tobacco classes. Instead, we have reserved § 1150.7(a)(2) and § 1150.9(a)(2) should a user fee assessment be applied to cigars and pipe tobacco and limited the definition of ''units of product'' in § 1150.3 by removing the reference to cigars or pipe tobacco. We did not delete cigars and pipe tobacco from the definition of ''class of tobacco products'' because that term is used in § 1150.7(b) describing our reallocation of user fees for any class of tobacco products (such as cigars or pipe tobacco) that is not deemed by FDA to be subject to regulation under chapter IX of the FD&C Act. If FDA deems cigars or pipe tobacco, we will respond to comments regarding these provisions and revise these user fee regulations.

We recognize that the issue of whether FDA has authority to assess user fees on future deemed products, other than cigars and pipe tobacco, is controversial. FDA intends to further explore issues related to user fee assessments on tobacco products that may be deemed subject to chapter IX of the FD&C Act by soliciting public comment. FDA will make any appropriate changes to the user fee regulations in a new rulemaking.

(Comment 2) Other comments raised concerns regarding user fee calculations

under section 919 in relation to specific products or classes of products that may be deemed subject to FDA's jurisdiction. For example, one comment stated that FDA should not adopt 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's current share of the market. This comment stated that small businesses may no longer be able to sell affected products, including dissolvables, electronic cigarettes, and cigars, but may still have to pay their share of their respective classes' user fees.

(Response) As discussed, certain tobacco products (including two classes—cigars and pipe tobacco—that are listed in section 919), are not currently subject to FDA's regulation under chapter IX of the FD&C Act. These comments relate to tobacco products that are not currently subject to chapter IX of the FD&C Act. Because this final rule is only addressing tobacco products that are currently subject to FDA's regulation, we do not address these comments at this time.

B. Use of the FETRA Framework

(Comment 3) One comment stated that FDA should calculate the applicable percentages for class and individual manufacturers on the basis of net domestic volume rather than gross domestic volume. The comment noted that ''FETRA's reliance on gross domestic volume overestimates the actual amount of product ultimately removed into domestic commerce, thereby producing inaccurate user fee assessments at both the class and individual [m]anufacturer levels.'' The comment indicated that inaccurate user fee assessments may result in overpayment by some manufacturers.

(Response) We disagree with this comment and will continue to rely on gross domestic volume in our user fee calculations. Section 919 of the FD&C Act directs us to calculate the applicable percentages of each class, and of each domestic manufacturer or importer within each class, by reference to FETRA (section 919(b)(2)(B)(ii) and (b)(4) of the FD&C Act). FETRA defines and relies on ''gross domestic volume'' to determine class assessments and allocations to each domestic manufacturer and importer within each class (7 U.S.C. 518d(a), (c)(2), and (e)(1)). We note that, while the use of gross rather than net domestic volume might increase an individual company's numerator, it would also increase the denominator for the class. We, therefore, do not think that use of gross domestic volume is likely to significantly affect an individual domestic manufacturer or importer unless there is a disproportionately large difference between a company's net domestic volume and its gross domestic volume as compared to other companies in the class.

(Comment 4) One comment stated that FDA should use the current Federal excise tax rate in Step A, not the 2003 excise tax rate used by USDA. The comment noted that, at the time the comment was submitted, this issue was the subject of ongoing litigation, and the comment urged FDA to make its own determination about which tax rate to use. This and other comments urged FDA to instead compute each class' percentage of the user fees based on the actual Federal excise taxes paid by each class during the relevant fiscal year. One comment supported the continued use of the 2003 excise tax rate, saying that FDA is bound by the FD&C Act to use those rates.

(Response) We disagree with the comments that suggested we use a method other than the 2003 maximum excise tax rate to determine the class allocation. Section 919(b)(2)(B)(ii) of the FD&C Act directs us to use, for the class allocations, the percentage determined under section 625(c) of FETRA (7 U.S.C. 518d). As discussed in the preamble to the proposed rule (78 FR 32581 at 32582), USDA determines the percentages under section 625(c) of FETRA by using the 2003 maximum Federal excise tax rate to convert the volume of each tobacco product class measured in different units (sticks and pounds) to a common metric: Dollar amounts. USDA used 2003 maximum excise tax rates because it determined that Congress used them as a conversion factor to create a common unit across all six classes of tobacco products subject to assessments under FETRA when Congress set the initial class allocations under FETRA. The 2003 maximum excise tax rate has been used since the inception of the TTPP to convert the volume of each tobacco product class to dollar amounts, from which USDA calculates the percentage for each class. This has been upheld as a reasonable interpretation of FETRA (*Philip Morris USA, Inc.* v. *Vilsack,* 736 F.3d 284 (4th Cir. 2013)).

Since the inception of FDA's tobacco user fee program, FDA has been using the class percentages calculated by USDA using this methodology. In this final rule, FDA is adopting the same approach as USDA for class allocations. Because section 919 relies on the FETRA class allocation methodology and provides for class allocation among the same tobacco product classes, it is reasonable for FDA to continue using the 2003 maximum Federal excise tax rates as a conversion factor (converting sticks and pounds to dollars). Continuing to use the 2003 rates also allows FDA, just as it allows USDA, to allocate the total user fees among the classes based on changes in each class' percentage of gross domestic volume over time. Because it is a fixed conversion factor, it will limit changes in user fee assessments to changes in volumes. Moreover, the changes from the 2003 rates to the 2009 rates were not proportionate among the classes. Thus, if FDA were to start using the 2009 rates after USDA's program sunsets, this would cause a change in class allocations that would not be limited to the changes in volume among the classes.

(Comment 5) One comment stated that FDA should use the actual units (e.g., sticks for cigarettes and cigars) removed from bonded storage to calculate market share within those classes of tobacco products (Step B) instead of the amount of Federal excise tax paid. The comment noted that using excise taxes to determine market share favors importers over domestic manufacturers because importers can sell cigars to distributors at a lower price than domestic manufacturers due to lower wages, taxes, and regulatory costs. The comment also noted that using excise taxes to calculate market share within a class of tobacco products (Step B) favors companies that do not accurately calculate excise tax.

(Response) This issue is relevant primarily for imposing user fees on cigar manufacturers and importers, which is not addressed in this final rule. Cigars are currently the only tobacco product for which variable excise taxes may be based on price of the product rather than a flat tax based on sticks or weight.[3] In accordance with FETRA, USDA calculates the percentage share of a domestic manufacturer or importer within a class by dividing the volume of tobacco products (in either sticks or pounds) for the manufacturer or importer by the total volume of tobacco products (in either sticks or pounds) for

[3] Under section 919(b)(5) of the FD&C Act, if user fee assessments were to be imposed on cigars, the statute requires that the percentage share of each domestic manufacturer or importer of cigars must be based on the excise taxes paid by a domestic manufacturer or importer over the course of the prior fiscal year rather than during the prior fiscal quarter.

that class. USDA uses excise taxes as a proxy for volume for all classes except cigars because the tax rate by volume is uniform within each of those classes. This final rule, in § 1150.9, follows that approach. For products for which excise taxes do not vary, there should be no difference in calculating individual assessments using excise taxes or actual units because a firm's percentage of the total class will remain the same. In addition, FDA will have information regarding both excise taxes paid and actual units removed for each domestic manufacturer and importer from information provided in Form FDA 3852 (Ref. 1). Therefore, FDA could check that excise taxes were calculated accurately.

C. FDA's Implementation

(Comment 6) Several comments urged FDA to consider the impact of the proposed rule on small manufacturers and importers. These comments suggested that FDA take steps to recognize ''differences in the scale and resources of regulated entities.''

(Response) FDA does recognize that domestic manufacturers and importers have varying levels of resources available. In an effort to minimize the need for additional resources and for continuity, the rule requires that domestic manufacturers and importers submit essentially the same information to FDA that they are currently submitting to USDA. In addition, actual user fee assessments are based on relative market share so that small domestic manufacturers and importers with fewer products in commerce will pay a relatively smaller share of the total assessment for the fiscal year.

(Comment 7) One comment recommended that FDA ''develop a schedule for periodically reevaluating and adjusting user fee percentage allocations'' for tobacco product classes as well as manufacturers and importers to ensure that allocations are fair and equitable.

(Response) FDA agrees, and our rule provides for adjustments for percentage allocations for both tobacco product classes and individual domestic manufacturers and importers. For tobacco product classes, § 1150.7 provides for yearly class allocations among the regulated classes of tobacco products. Also, § 1150.9(a) provides for calculation of assessments within each class on a quarterly basis, based on information from the prior quarter. In addition, § 1150.9(b) explains that on an annual basis, FDA will make any necessary adjustments for individual domestic manufacturers and importers if needed to account for any corrections, such as the addition of one or more domestic manufacturers or importers that were not included in relevant calculations under § 1150.9(a).

(Comment 8) Several comments stated that refunds for overpayment of user fees should include interest on the amount that was incorrectly assessed. Some comments indicated that the Internal Revenue Code provides for interest on overpayments (26 U.S.C. 6611(a)) and that FDA should adopt this approach or a similar approach to refunds.

(Response) FDA disagrees with these comments. In order to recover interest from the United States, there must be an explicit waiver of sovereign immunity related to interest payments (see, e.g., *United States* v. *N.Y. Rayon Importing Co.,* 329 U.S. 654, 659 (1947)). Congress alone has authority to waive the government's sovereign immunity. The Internal Revenue Code provision cited by some comments is specific to the payment of internal revenue tax and provides that interest ''shall be allowed and paid upon any overpayment in respect of any internal revenue tax.'' The TTPP also explicitly requires that interest be paid on refunded amounts (7 U.S.C. 518d(j)). In contrast, the FD&C Act does not require FDA to pay interest on refunds for overpayment of tobacco product user fees. Moreover, the FD&C Act does not require FDA to pay interest on refunds for overpayment in any other user fee context, and FDA does not pay interest on such refunds.

(Comment 9) Several comments indicated that FDA should clarify the process by which manufacturers and importers may appeal a user fee assessment. One comment detailed the provisions that FDA should include in an appeals process (e.g., establishing timeframes for such challenges as well as FDA review and response, putting the disputed fee in an escrow account pending appeal). This comment also requested that the rule specifically permit judicial review in U.S. district court of FDA's decisions regarding disputes. Another comment suggested that FDA adopt USDA's dispute resolution process for user fees.

(Response) To address some of the concerns raised by the comments, FDA has added information to § 1150.15 on how to submit a dispute. FDA has also revised § 1150.15 to clarify that the dispute must be received by FDA within 45 days of the date on FDA's invoice. However, we believe that establishing additional requirements to the appeals process is unnecessary at this time. To date, FDA has received few requests for corrections regarding individual user fees. Accordingly, FDA has provided a framework in § 1150.15 on where, when, and how to submit a dispute and request for additional review under § 10.75. Should the need arise, FDA may issue additional information through a guidance document specific to tobacco product user fee assessment disputes.

In addition, and of its own initiative, FDA has added the requirements that disputes be legible (FDA must be able to read the document) and in English. These requirements will help expedite FDA's review of the dispute and request for additional review.

(Comment 10) One comment stated that FDA should clarify the data verification provisions for user fees. The comment indicated support for the use of third-party data sources for the purpose of identifying manufacturers and importers who are not providing FDA with market share information (nonreporters) or who understate that information (underreporters). However, the comment noted that third-party data should be used only to identify nonreporters and underreporters within the six classes and should not be used to calculate actual market shares (which must be calculated using excise tax data). This comment also asked FDA to clarify that third-party data could be used to calculate market share for tobacco products not within the six classes if FDA determines there is no better alternative available.

(Response) FDA agrees that it can use information available to the Agency to help ensure that domestic manufacturers and importers are providing the information required under this rule. As stated in § 1150.5(a) FDA will use information submitted to FDA as required under § 1150.5 and any other available information, as the Agency determines appropriate, to make user fee assessments. We do not agree that it is necessary to describe or limit the sources of data that FDA might use.

(Comment 11) One comment suggested that FDA obtain data about product removals directly from the Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB). The comment stated that monthly data submissions are unnecessary and unduly burdensome since this information is already collected by TTB. The comment indicated that FDA should require manufacturers to execute a release or waiver permitting TTB to report this information to FDA and that failure to execute such a release or waiver could be construed as an admission of adulteration under section 902(4) of the FD&C Act. However, the comment noted that manufacturers of regulated tobacco products that do not fit within TTB's excise tax structure

could submit information directly to FDA. Another comment suggested that FDA seek a legislative amendment to ensure that FDA has access to excise tax data. In contrast, one comment supported FDA's transition plan for submitting data and noted that it should not be burdensome because manufacturers and importers are familiar with the reporting of this information and the submissions will continue to be made to a single Federal Agency.

(Response) We agree with the comment that, because the rule requires that domestic manufacturers and importers submit to FDA the same information that they have been submitting to USDA (i.e., a summary form supported by the relevant tax forms), the impact of this rule should be minimal and not unduly burdensome. We also note that there are statutory limitations on the access and use by other Federal Agencies of the data collected by TTB, and those limitations preclude us from solely using that data to implement section 919 of the FD&C Act. The summary form will enable us to efficiently identify the amount of tobacco product removed and subject to Federal excise tax, and the supporting tax forms will enable us to verify the accuracy of the information on the summary form. We believe that submission of information directly to FDA regarding removals and imports is important to ensuring that we have the information necessary to efficiently and accurately calculate the amount of user fees assessed.

IV. Legal Authority

Section 919(b)(7) of the FD&C Act requires FDA to ensure that 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) of the FD&C Act, 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. 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 to 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. 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. 601–612), 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). The Agency believes that this final rule is not 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 $141 million, using the most current (2012) 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 primary baseline, starting in fiscal year 2015, FDA would obtain the information necessary for collecting user fees directly from Federal Agencies (other than USDA) that collect such information. Compared with this baseline, this final rule will impose private costs on industry to submit data to FDA on a monthly basis, with 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 also allows FDA to be in control of the data needed for calculating and billing user fees and resolves impediments that may otherwise exist to FDA's ability to use the data for its intended purpose. Compared with other possible baseline scenarios, this final rule can be expected to eliminate the potential need for additional legislation and allow the collection of user fees after 2014 to proceed more smoothly than it could without legislation.

Compared to the primary baseline, the estimated one-time private sector transition cost is $159.60 per manufacturer or importer, including small manufacturers and importers, and the annual compliance cost is $2,553.60. 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. 2 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 (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 Tobacco Products.

Description: This final rule requires each tobacco product domestic manufacturer and importer to submit to FDA information needed to calculate

and assess user fees under the FD&C Act.

The USDA has been collecting information from manufacturers and importers to calculate percentage share for its purposes, and providing FDA with the data FDA needs to determine user fee assessments under the FD&C Act. USDA will cease collecting this information starting in fiscal year 2015. Consistent with the requirements of the FD&C Act, this final rule would continue the submission of this information, but to FDA rather than USDA, and thus would ensure 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 is now required by USDA under FETRA, in this final rule FDA requires domestic manufacturers and importers of tobacco products to submit a form each month 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 tobacco products.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
1150.5(a), (b)(1), (b)(2), and FDA Form 3852; General identifying information provided by manufacturers and importers of FDA regulated tobacco products and identification and removal information (monthly)	200	12	2,400	3	7,200
1150.5(b)(3) Certified Copies (monthly)	200	12	2,400	1	2,400
1150.13 Submission of user fee information with user fee payment (identifying information, fee amount, etc.) (quarterly)	100	4	400	1	400
1150.15(a) Submission of user fee dispute (annually)	10	1	10	10	100
1150.15(d) Submission of request for further review of dispute of user fee (annually)	5	1	5	10	50
Total					10,150

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 describes the annual reporting burden of 10,150 hours as a result of the provisions set forth in this final rule. Our estimated number of respondents is based on information we received from USDA on the number of reports it receives from domestic manufacturers and importers each month. The estimate of 200 respondents reflects both reports of no removal into domestic commerce and reports of removal of tobacco product into domestic commerce. The estimate of 100 respondents reflects an average number of domestic manufacturers and importers who may be subject to the payment of fees each fiscal quarter. Although there were no comments on the number of appeals and requests for further review, after discussing internally, we increased our estimate of the number of appeals from 1 to 10, and requests for further review from 1 to 5 in an abundance of caution in case there is an increase in requests for review during the transition from USDA to FDA.

For § 1150.5(a), (b)(1), and (b)(2), FDA estimates that 200 domestic manufacturers and importers will each submit identifying information (e.g., mailing address, telephone number, email address) and summarized tax information on a monthly basis (12 submissions annually) on Form FDA 3852, resulting in a total burden of 7,200 hours. For § 1150.5(b)(3), FDA estimates that 200 domestic manufacturers and importers will each submit, on a monthly basis (12 times annually), certified copies of the returns and forms that relate to the removal of tobacco products into domestic commerce and the payment of Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986, resulting in a total burden of 2,400 hours.

For § 1150.13, FDA estimates that 100 domestic manufacturers and importers will be submitting user fee payments on a quarterly basis. Therefore, the number of burden hours for this section is 400 hours. FDA estimates that approximately 10 of those respondents assessed user fees will dispute the amounts under § 1150.15(a), for a total amount of 100 hours. FDA also estimates that of those who dispute their user fees, five will ask for further review by FDA under § 1150.15(d), for a total amount of 50 hours. Total burden hours for this rule are 10,150 hours (7,200 + 2,400 + 400 + 100 + 50).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. The requirements were approved and assigned OMB control number 0910–0749. This approval expires on June 30, 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.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final 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, the Agency has concluded that the final 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 (see **ADDRESSES**) 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 in this reference section, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Form FDA 3852.

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

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, chapter I of title 21 is amended by adding part 1150 to subchapter K to read as follows:

PART 1150—USER FEES

Sec.

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

§ 1150.1 Scope.

This part establishes requirements related to tobacco product user fees under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s). The total amount of user fees may not exceed the amount specified for that fiscal year in section 919(b) of the Federal Food, Drug, and Cosmetic Act. All domestic manufacturers and importers of tobacco products are required to pay to FDA their percentage share of the total assessment for a fiscal year.

§ 1150.3 Definitions.

The following definitions are applicable to this part:

Class of tobacco products means each of the following types of tobacco products as defined in 26 U.S.C. 5702 and for which taxes are required to be paid for the removal of such into domestic commerce: Cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

Domestic manufacturer means a person who is required to obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury with respect to the production of tobacco products under title 27 of the Code of Federal Regulations.

Fiscal year quarter means a quarter in a fiscal year (the fiscal year is October 1 through September 30). The fiscal year quarters are October 1–December 31, January 1–March 31, April 1–June 30, and July 1–September 30.

Importer means a person who is required to obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury with respect to the importation of tobacco products under title 27 of the Code of Federal Regulations.

Total assessment means the total amount of user fees (in dollars) authorized to be assessed and collected for a specific fiscal year under section 919 of the Federal Food, Drug, and Cosmetic Act.

Units of product means:

(1) The number of sticks for cigarettes, or

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

Units of product removed and not tax exempt means the units of product:

(1) Removed (as defined by 26 U.S.C. 5702), and

(2) Not exempt from Federal excise tax under chapter 52 of title 26 of the United States Code at the time of their removal under that chapter or the Harmonized Tariff Schedule of the United States.

Yearly class allocation means the amount of user fees (in dollars) assessed for a class of tobacco products for a particular fiscal year.

§ 1150.5 Required information.

(a) *General.* Each domestic manufacturer and importer of tobacco products 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 must submit the information described in this section for such products each month beginning October 2014, and the information must be received by FDA no later than the 20th day of each month. The information must be submitted using the form that FDA provides. The information must be submitted even if the domestic manufacturer or importer had no removals subject to tax during the prior month. FDA will use the information submitted under this section and any other available information, as FDA determines appropriate, to make tobacco product user fee assessments.

(b) *Contents.* Each domestic manufacturer and importer must submit the following:

(1) *Identification information.* (i) Its name and the mailing address of its principal place of business;

(ii) The name and a telephone number including area code of an office or individual that FDA may contact for further information;

(iii) The email address and postal address at which it wishes to receive notifications FDA sends under this part;

(iv) The Alcohol and Tobacco Tax and Trade Bureau (TTB) Permit Number(s); and

(v) The Employer Identification Number(s) (EIN).

(2) *Removal information.* The units of product, by class, removed and not tax exempt for the prior month and the Federal excise tax it paid, by class, for such removal.

(i) This information must be reported for each TTB tobacco permit.

(ii) If the domestic manufacturer or importer did not remove any amount of tobacco product, it must report that no tobacco product was removed into domestic commerce.

(3) *Certified copies.* Certified copies of the returns and forms that relate to:

(i) The removal of tobacco products into domestic commerce (as defined by section 5702 of the Internal Revenue Code of 1986); and

(ii) The payment of the Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986.

§ 1150.7 Yearly class allocation.

For each fiscal year, FDA will allocate the total assessment among the classes of tobacco products.

(a) *Calculation.* FDA will calculate the percentage shares for each class as follows:

(1) 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 applicable class or subclass (class dollar figure).

(2) [Reserved]

(3) FDA will total the class dollar figures for all tobacco classes for the most recent full calendar year (total dollar figure).

(4) FDA will divide the class dollar figure by the total dollar figure to determine the percentage share for each class.

(5) FDA will calculate the allocation for each class of tobacco products by multiplying the percentage share for each class by the total assessment.

(b) *Reallocation.* For any class of tobacco products that is not deemed by FDA to be subject to regulation under chapter IX of the Federal Food, Drug, and Cosmetic Act, the amount of user fees that would otherwise be assessed to such class of tobacco products will be reallocated to the classes of tobacco products that are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act in the same manner and based on

the same relative percentages otherwise determined under paragraph (a) of this section.

§ 1150.9 Domestic manufacturer or importer assessment.

Each quarter, FDA will calculate the assessment owed by each domestic manufacturer or importer for that quarter.

(a) *Calculation.* (1) For each class of tobacco products, 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) [Reserved]

(3) If the percentage share calculated for a domestic manufacturer or importer in this section, as applicable, is less than 0.0001 percent, the share is excluded from the assessment for that class of tobacco products.

(4) Within each class of tobacco products, the assessment owed by a domestic manufacturer or importer for the quarter is the yearly class allocation, determined as described in § 1150.7, divided by four, multiplied by the domestic manufacturer's or importer's percentage share, truncated to the fourth decimal place, for that class of tobacco products.

(b) *Adjustments.* Annually, FDA will make any necessary adjustments to individual domestic manufacturer or importer assessments if needed to account for any corrections (for example, to include domestic manufacturers or importers that were not included in a relevant assessment calculation).

§ 1150.11 Notification of assessments.

(a) *Notification.* No later than 30 calendar days before the end of each fiscal year quarter, FDA will notify each domestic manufacturer and importer of the amount of the quarterly assessment imposed on the domestic manufacturer or importer.

(b) *Content of notification.* The notification under paragraph (a) of this section will include the following:

(1) The amount of the quarterly assessment imposed on the domestic manufacturer or importer and the date that payment of the assessment must be received by FDA;

(2) Class assessment information, including each class' initial percentage share, the reallocation amount (if any) and each class' percentage share after any such reallocation, and the quarterly assessment for each class;

(3) Domestic manufacturer or importer assessment information, including the domestic manufacturer's or importer's percentage share of each relevant class of tobacco products and invoice amount;

(4) Any adjustments FDA has made under § 1150.9(b);

(5) The manner in which assessments are to be remitted to FDA;

(6) Information about the accrual of interest if a payment is late; and

(7) Information regarding where to send a dispute and when it needs to be sent.

§ 1150.13 Payment of assessments.

(a) Payment of an assessment must be received by FDA no later than the last day of each fiscal year quarter.

(b) Payments must be submitted to FDA in U.S. dollars and in the manner specified in the notification.

(c) Except as provided in paragraph (d) of this section, if an assessment is not received by the last day of the fiscal year quarter, FDA will begin assessing interest on the unpaid amount in accordance with 31 U.S.C. 3717.

(d) If FDA does not send the notification described in § 1150.11(a) 30 calendar days before the end of a quarter, no interest will be assessed by FDA under paragraph (c) of this section until 30 calendar days have elapsed from the date FDA sent notification of the amount owed.

(e) If a domestic manufacturer or importer disputes the amount of an assessment, it must still pay the assessment in accordance with paragraphs (a) and (b) of this section.

§ 1150.15 Disputes.

(a) A domestic tobacco manufacturer or importer may dispute an FDA assessment. The dispute must include the basis for the dispute, and the dispute must be:

(1) Submitted in writing;

(2) Received by FDA no later than 45 days after the date on the assessment notification;

(3) Legible and in English; and

(4) Sent to the address found on our Web site (*http://www.fda.gov/tobaccoproducts*).

(b) If FDA determines that there was an error related to the assessment and the assessment was too high, FDA will refund the amount assessed in error to the domestic manufacturer or importer.

(c) FDA will provide a dated, written response, and its response will provide information about how to submit a request for further Agency review.

(d) A request for further Agency review under § 10.75 of this chapter may be submitted. Such a request must be submitted in writing by the domestic manufacturer or importer and received by FDA within 30 days from the date on FDA's response. The request for further Agency review must be legible, in English, and submitted to the address found on our Web site (*http://www.fda.gov/tobaccoproducts*).

§ 1150.17 Penalties.

(a) Under section 902(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387b), a tobacco product is deemed adulterated if the domestic manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer by the later of the date the assessment is due, 30 days from the date FDA sent notification of the amount owed, or 30 days after final Agency action on a resolution of any dispute as to the amount of the fee.

(b) Under section 902(4) of the Federal Food, Drug, and Cosmetic Act, a tobacco product is deemed adulterated if the domestic manufacturer or importer of the tobacco product fails to report the information required by § 1150.5 to calculate assessments under this part.

(c) The failure to report the information required by § 1150.5 to calculate assessments under this part is a prohibited act under section 301(e) of the Federal Food, Drug, and Cosmetic Act.

(d) Information submitted under § 1150.5 is subject to 18 U.S.C. 1001 and other appropriate civil and criminal statutes.

Dated: July 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16153 Filed 7–9–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9674]

RIN 1545–BM07

Guidelines for the Streamlined Process of Applying for Recognition of Section 501(c)(3) Status

Correction

In rule document 2014–15623 on pages 37630–37632 of the issue of Wednesday, July 2, 2014 make the following correction:

PART 1—INCOME TAXES

On page 37631, in the third column, in the 26th line from the bottom,