(2) For airplanes that have, as of the effective date of this AD, accumulated more than 18,000 total flight hours, but 23,400 total flight hours or less: Replace within 6,600 flight hours after the effective date of this AD.

(3) For airplanes that have, as of the effective date of this AD, accumulated more than 23,400 total flight hours, but 28,500 total flight hours or less: Replace before the accumulation of 30,000 total flight hours.

(4) For airplanes that have, as of the effective date of this AD, accumulated more than 28,500 total flight hours: Within 1,500 flight hours after the effective date of this AD.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, 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 ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone 516–228–7300; fax 516–794–5531. 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. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(i) Related Information

(1) Refer to MCAI Canadian Airworthiness Directive CF–2013–03, dated February 5, 2013; and Bombardier Service Bulletin 670BA–27–064, dated December 11, 2012; for related information.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may review copies of the referenced service information at the 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.

Issued in Renton, Washington, on May 22, 2013.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–12897 Filed 5–30–13; 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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing this proposed rule that would require 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, we are proposing to require the submission of this information to FDA instead of USDA. We are taking this action to ensure that FDA continues to have the information we need to calculate, assess, and collect user fees.

DATES: Submit either electronic or written comments on the proposed rule by August 14, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by July 1, 2013 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–0920 and/or Regulatory Information Number (RIN) 0910–AG81, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand Delivery/Courier* (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No(s). and RIN for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy Boocker or Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373. *Nancy.Boocker@fda.hhs.gov* or *Annette.Marthaler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Public Law 111–31, 123 Stat. 1776). Section 919(a) of the FD&C Act (21 U.S.C. 387s(a)) requires FDA to ''assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products'' subject to the tobacco product provisions of the FD&C Act (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.[1] The class allocation is based on each tobacco product class' volume of tobacco products removed [2] into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its share of the market 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.'' 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, 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) through which eligible former tobacco quota holders and tobacco producers receive payments in 10 equal installments in each fiscal year 2005 through 2014. The Farm Service Agency (FSA) of the USDA has been the organization responsible for implementing FETRA on behalf of the Commodity Credit Corporation (CCC) of the USDA. 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. This 40th quarterly assessment will be determined by using the same adjusted market share of an entity that was used to determine the 39th quarterly assessment (market activity during April 1 to June 30, 2014).

Under a Memorandum of Understanding between FDA and USDA (Ref. 1), USDA has been providing FDA with the information on percentage share by class of tobacco products and by individual company within each tobacco product class. Under FETRA, the authority to collect assessments ends September 30, 2014; however, USDA will still collect the July, August, and September 2014 monthly reports with the same established monthly deadline, so the 40th quarter's assessment can later be '''trued-up''' or adjusted to reflect the actual market share of domestic tobacco manufacturers and importers for the 40th quarter. Section 919(b)(7) of the FD&C Act requires that no later than fiscal year 2015, we ensure we are able to make the determinations necessary for assessing tobacco product user fees.

A. Two-Step Process To Calculate Quarterly Assessments

Both the USDA 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 specified 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 and 1463.5; and section 919(b)(2)(B) of the FD&C Act).
- 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 (sections 625(e) through (h) of FETRA; 7 CFR 1463.7; and sections 919(b)(3) through (b)(5) of the FD&C Act).

1. Step A

For Step A, FETRA specified the initial allocation among the six classes of tobacco products. For this initial calculation, USDA has determined that Congress used publicly available calendar year 2003 relevant class volume numbers (sticks [3] for cigarettes and cigars, pounds for the other classes) from the Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB) and multiplied those numbers by the maximum 2003 Federal excise tax rates for each class of tobacco products (Ref. 2). In this fashion, the volume of each tobacco product class was converted from differing bases (sticks and pounds) to a common metric: Tax dollar amounts. The tax dollar amounts were added together for a six class total. The allocation for each class of tobacco products was its percentage contribution to the six-class total (Ref. 2 at pp. 4–7). As directed by FETRA, USDA adjusts these allocations annually to reflect changes in the gross domestic volume of each tobacco product class, and it does so using the same methodology that Congress used to make the initial allocation (Ref. 2 at pp. 8–10). Specifically, USDA determines the gross domestic volume of each tobacco product class by multiplying the maximum 2003 Federal excise tax rate for each class by the volume information from TTB for the most recent full calendar year. In other words, for fiscal year 2012, USDA

[1] As discussed later in this section, two of these classes (cigars and pipe tobacco) are not currently subject to regulation under chapter IX of the FD&C Act. Domestic manufacturers and importers are not required to pay user fees for these classes of tobacco products unless, by regulation, FDA deems them subject to FDA's jurisdiction.

[2] 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.''

[3] In this document, the number of ''sticks'' is used to refer to the number of individual cigarettes or cigars.

calculates gross domestic volume for each class of tobacco products based on information for calendar year 2010.

As discussed previously in this document, section 919(b)(2)(B)(ii) of the FD&C Act provides that the applicable percentage of each class of tobacco products will be the percentage determined under section 625(c) of FETRA.

2. Step B

Once the allocation to each class of tobacco products is determined, Step B determines the user fee to be assessed and collected from each domestic manufacturer and importer within that class. So it can allocate the assessment for each class of tobacco products among the domestic manufacturers and importers in each class, USDA collects information from each domestic manufacturer and importer on the volume of taxable removals [4] (sticks or pounds) and the resulting excise taxes it has paid for those removals (7 CFR 1463.6). USDA collects this information monthly using a form it has developed (*http://forms.sc.egov.usda.gov/efcommon/eFileServices/eForms/CCC974.PDF*) (Ref. 3). Along with this form, each domestic manufacturer and importer is also required to submit certified copies of specified tax returns and forms (see section 625(h) of FETRA). For domestic manufacturers, these documents are TTB Form 5000.24 (Excise Tax Return) and TTB Form 5210.5 (Report, Manufacturer of Tobacco Products or Cigarette Papers and Tubes). For importers, these documents are Department of Homeland Security, U.S. Customs and Border Protection (CBP) Form 7501 (Importer Entry Summary) and TTB Form 5220.6 (Monthly Report, Tobacco Products or Processed Tobacco Importer). In accordance with FETRA, USDA calculates the percentage share of a domestic manufacturer or importer within a class of tobacco products by dividing the volume of tobacco products (in either sticks or pounds, depending on the class) attributable to an entity by the total volume of tobacco products (in either sticks or pounds) for that class. Excise taxes paid can be used as a proxy for volume when the tax rate by volume (sticks or pounds) is uniform for the whole class (which is the case for all classes except cigars). USDA then multiplies the percentage by the assessment amount attributed to the class of tobacco products to determine the specific firm's assessment. (See Ref. 2 at pp. 10–15.)

For Step B, section 919(b)(4) of the FD&C Act requires FDA to allocate the assessment of user fees for each class of tobacco products among the tobacco product manufacturers and importers in those classes using the percentages determined under section 625(e) through (h) of FETRA.

B. Specific Considerations and Processes for User Fees Under Section 919 of the FD&C Act

The calculation of user fees under section 919 of the FD&C Act does differ from FETRA in some important respects. First, we may not assess a user fee on a class of tobacco products unless that class of tobacco products is either listed in section 901(b) of the FD&C Act (21 U.S.C. 387a(b)) (cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco [5]) or has been deemed by FDA in a regulation under section 901(b) to be subject to chapter IX of the FD&C Act. For those classes of tobacco products that are not deemed by FDA to be subject to chapter IX of the FD&C Act, with respect to Step A of the assessment calculation, the amount of user fees that otherwise would be assessed to such class is reallocated to the classes of tobacco products that are subject to chapter IX of the FD&C Act (section 919(b)(2)(B)(iv) of the FD&C Act).

Second, with respect to Step B of the assessment calculation, section 919 of the FD&C Act provides that if a user fee assessment is imposed on cigars, the percentage share of each domestic manufacturer and importer of cigars shall be based on the excise taxes paid by such domestic manufacturer or importer during the prior fiscal year (section 919(b)(5) of the FD&C Act).

As required by the FD&C Act, user fees are to be assessed and collected each quarter of each fiscal year and the total amount assessed and collected is the amount specified in section 919(b). FDA makes a determination of the total user fee to be paid by each domestic manufacturer and importer each fiscal quarter (four times a year), using the information FDA currently receives from USDA, and notifies each entity of its quarterly assessment by invoice. The invoice from FDA currently includes information about how to remit payments and accrual of interest if a payment is not received by the date due.

The authority to collect the last assessment under FETRA ends September 30, 2014; however, USDA plans to provide the original market share activity for the 39th and 40th quarter as well as the ''trued-up'' or revised market share to FDA on the same time schedule as any other quarterly assessment. Because we anticipate that after USDA's 40th quarterly assessment FDA will no longer receive the information from USDA that we currently use to calculate the tobacco product user fee assessments,[6] we are issuing this proposed rule that would require the submission of information to FDA.

II. Description of the Proposed Rule

As discussed in section I of this document, section 919 of the FD&C Act establishes a user fee assessment and collection process that references the FETRA framework for determining allocations among classes of tobacco products and among individual domestic manufacturers and importers within each class. The proposed rule is intended to ensure that FDA collects from domestic manufacturers and importers information necessary to make these allocations and to assess user fees for domestic manufacturers and importers. The following sections discuss in more detail the proposed rule and FDA's rationale for the proposed sections.

A. General Principles

This proposed rule uses the TTPP framework, as implemented by USDA. We believe that adopting an approach similar to the TTPP regulations is consistent with the direction of section 919 of the FD&C Act. For example, section 919(b)(2)(B)(ii) of the FD&C Act directs that when allocating user fee assessments to classes of tobacco products (Step A), FDA shall use the percentage as determined under section 625(c) of FETRA. Similarly, section 919(b)(4) of the FD&C Act directs that when determining the user fee by company (Step B), FDA shall use the percentage as determined under subsections (e) through (h) of section 625 of FETRA. Thus, the proposed rule uses the same approach as USDA for collecting data and making allocations among firms. Because domestic manufacturers and importers are

[4] FETRA defines removal with reference to 26 U.S.C. 5702 (see 7 U.S.C. 518d(a)(2)).

[5] Smokeless tobacco, as defined in section 900(18) of the FD&C Act, includes snuff and chewing tobacco as these classes are defined in 26 U.S.C. 5702; thus, the classes of snuff and chewing tobacco are currently subject to user fees.

[6] With respect to the quarterly assessments issued by USDA on September 1, 2014, the user fee allocations will be based on percentage share during the April 1 to June 30, 2014, quarter (7 CFR 1463.6). The original 40th quarter's market share will be ''trued-up'' or revised after receipt of the July, August, and September 2014 monthly reports during the 2014 annual revision and this information will then be provided to FDA.

familiar with the TTPP, using this approach should help minimize confusion about the submission requirements and the methodology used to make the calculations of user fee assessments. While the proposed rule uses the TTPP framework to a large extent, it provides additional explanation of precisely how FDA intends to make the Step A and Step B calculations.

This proposed rule varies from USDA's regulation implementing the TTPP in certain respects to reflect differences between FETRA and the FD&C Act. These differences, however, do not affect the types of data that domestic manufacturers and importers would submit to FDA. For example, one difference reflected in the proposal is that the total yearly user fee is specified in the FD&C Act (section 919(b)(1) of the FD&C Act), whereas for the TTPP, USDA calculates the total assessments for a year based on actual annual program costs (section 625(b)(2) of FETRA). Another example relates to disputes. FETRA provides a specific hearing process related to challenges of TTPP assessments (see section 625(i) of FETRA and 7 CFR 1463.11). Section 919 of the FD&C Act neither references this section of FETRA nor provides a particular dispute process. Thus, while the proposed rule contains some provisions relating to disputes regarding the amount of the fee assessments (discussed in more detail in section II.G of this document), the proposed provisions differ from those in the TTPP program.

B. Scope and Definitions

The proposed rule includes a scope section (proposed § 1150.1 (21 CFR 1150.1)) that explains how the regulation would relate to the collection and assessment of user fees and how it would apply to domestic manufacturers and importers of tobacco products. In addition, the proposal includes a definitions section that would help clarify the meaning of terms used throughout the proposed rule. Several of the terms are similar to terms used in the TTPP regulations (7 CFR part 1463).

The following terms are defined in proposed § 1150.3:

Class of tobacco products. We are proposing to define ''class of tobacco products'' as cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. These are the classes of tobacco products named in section 919(b)(2)(B)(i) of the FD&C Act. They are also the same six classes of tobacco products that have been subject to TTPP assessments under FETRA and, as such, the classes for which there is a method for determining the applicable percentages under FETRA, both for the classes and individual entities within the classes. The FETRA percentage is based on gross domestic volume, which is defined as the volume of tobacco products removed within the meaning of the Internal Revenue Code (section 625(a)(2) of FETRA). Under the Internal Revenue Code, the six classes are the only ones defined as ''tobacco products'' that are removed and that are subject to the excise tax requirements (26 U.S.C. 5701 and 5702(c) and (j)). Therefore, we are not including other classes of tobacco products in the proposed rule, even though these six classes do not encompass all tobacco products as that term is defined in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)).[7] While some of these classes have definitions in the FD&C Act, such as the definition of ''cigarette'' in section 900(3) of the FD&C Act, we are proposing to use the definitions in 26 U.S.C. 5702 because these are the definitions currently used in determining the applicable percentages for the purpose of user fee assessments.[8]

Domestic manufacturer and *importer.* We are proposing to define the term ''domestic manufacturer'' as a person who is required to obtain a permit from TTB with respect to the production of tobacco products under title 27 of the Code of Federal Regulations (CFR). We are proposing to define ''importer'' as a person who is required to obtain a permit from TTB with respect to the importation of tobacco products under title 27 of the CFR. The proposed use of two separate definitions would differ from some FD&C Act provisions that use the single term ''tobacco product manufacturer'' to refer to both manufacturers and importers. FDA views use of the terms domestic manufacturer and importer in this proposed rule as consistent with the language of section 919 of the FD&C Act, which uses the terms manufacturer and importer throughout. FDA is proposing to use the term ''domestic manufacturer'' instead of ''manufacturer'' in proposed part 1150 because the tobacco industry is familiar with the former term in the context of submitting information for assessment purposes.

Fiscal year quarter and *total assessment.* We are proposing to define the term ''fiscal year quarter'' as a quarter in a fiscal year (the fiscal year is October 1 through September 30). We are proposing to define ''total assessment'' as the total amount of user fees (in dollars) authorized to be assessed and collected for a specific fiscal year under section 919 of the FD&C Act. Both terms are specific to FDA's implementation of section 919 of the FD&C Act.

Units of product and *units of product removed and not tax exempt.* We are proposing to define ''units of product'' as the number of sticks for cigarettes and cigars, or the weight measured in pounds for snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. We are proposing to define ''units of product removed and not tax exempt'' as 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 at the time of their removal under that chapter or the Harmonized Tariff Schedule of the United States.

Yearly class allocation. We are proposing to define the term ''yearly class allocation'' as the amount of user fees (in dollars) to be assessed for a class of tobacco products for a particular year.

C. Required Information

The proposed rule includes a section (proposed § 1150.5) describing the information that domestic manufacturers and importers would be required to submit to FDA. The proposed requirement would provide continuity to domestic manufacturers and importers as it would require them to submit essentially the same information to FDA that they are currently submitting to USDA. This information would provide FDA with the information we need to calculate the user fee amount to be assessed and collected from each domestic manufacturer and importer.

To determine the percentage share allocated to each class of tobacco products and then to determine the percentage share allocated to each domestic manufacturer and importer within each class, we need the same information that USDA uses to determine these percentages. USDA requires each domestic manufacturer and importer to submit certain summary information each month, which is reported on form CCC–974 (see 7 CFR 1436.6 and Ref. 3). USDA also requires

[7] Section 201(rr)(1) of the FD&C Act states: ''The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).''

[8] Although FDA has not deemed cigars to be subject to its jurisdiction, roll-your-own tobacco for cigars is part of the roll-your-own tobacco class, as defined in 26 U.S.C. 5702. Thus, we have considered roll-your-own tobacco for cigars to be subject to user fees under the roll-your-own tobacco class.

that each domestic manufacturer and importer of tobacco products submit a certified copy of certain returns or forms filed with a Federal Agency. The returns or forms described are those that relate to: (1) The removal of tobacco products into domestic commerce (as defined by section 5702 of the Internal Revenue Code of 1986) and (2) the payment of the taxes imposed under chapter 52 of the Internal Revenue Code (section 625(h) of FETRA).

Domestic manufacturers and importers are not required to pay user fees for the classes of tobacco products that have not been deemed, by regulation, to be subject to FDA's jurisdiction (*i.e.,* cigars, pipe tobacco). We are proposing that these domestic manufacturers and importers would not be required to submit information under proposed § 1150.5 unless and until they are deemed by regulation to be subject to chapter IX of the FD&C Act. We tentatively conclude that we can assess and collect the appropriate user fee amounts without such information.

1. Identifying Information

We are proposing to require domestic manufacturers and importers of tobacco products to provide to FDA summary information each month. Each domestic manufacturer or importer would submit identifying information, including its name and address, the name and telephone number of a contact, an email address or postal address for FDA notifications, its TTB permit number, and its Employer Identification Number (EIN).

2. Removals

We are proposing to require the submission of information regarding the total amount of tobacco products removed into domestic commerce in the prior month and the Federal excise taxes paid for those removals. The proposed rule would require monthly reports from all domestic manufacturers and importers. As is currently required by USDA, entities that had no removals subject to tax during the reporting period would be required to report that they had no removals. This type and frequency of reporting would be almost identical to what USDA currently collects on its CCC–974 form. Moreover, FDA intends to have available to domestic manufacturers and importers a form similar to USDA's CCC–974 but with changes reflecting that the information is submitted to FDA (Ref. 8).

3. Certified Copies of Returns and Forms

We are proposing to require domestic manufacturers and importers to submit each month certified copies of the returns or forms related to the removal of tobacco products into domestic commerce and the payment of excise taxes. The proposed rule refers to the reports and forms by reference to the applicable Internal Revenue Code authority. Because the specific names of reports and forms may change over time, we did not name reports or forms in the proposed rule. We instead intend to specify the form names in our quarterly notification of assessments to domestic manufacturers and importers and on our Web site (*www.fda.gov/TobaccoProducts*). Currently, the forms are: TTB Form 5220.6; TTB Form 5210.5; TTB Form 5000.24; and CBP Form 7501.

Collecting the required information would enable FDA to determine allocations and verify the monthly summary information on which the allocations are based so we can accurately assess and collect user fees from domestic manufacturers and importers. As has been USDA's approach, submission of the information in a summary form along with the supporting documents (copies of the relevant tax forms) would help ensure that we are able to efficiently and accurately identify the amount of tobacco product removed and subject to Federal excise tax. We believe the information proposed to be required would provide the information the Agency needs to effectively implement section 919 of the FD&C Act. The burden on reporting entities should be relatively low because they would be submitting a form they are already required to submit under separate laws along with a summary of information from that form.

The proposed rule would require that these entities submit to FDA this information beginning with the October 2014 monthly report to ensure that we continue to be able to accurately determine the tobacco product class allocation and the amount owed by each domestic manufacturer and importer. We specify this date in the proposed rule because we anticipate USDA will cease collecting the information after the September 2014 monthly report. We do not intend to overlap in the collection of this information because the information collected by USDA will continue to be available to FDA.

D. Methodology

1. Yearly Class Allocations

The proposed rule includes a section (proposed § 1150.7) describing how we would allocate the total assessment among each class of tobacco products (Step A). As described in the proposed rule, FDA would determine the yearly class allocation using publicly available tax data and information published by TTB about volumes of products removed. If the TTB information is no longer available, we would rely on information from copies of the returns or forms that would be submitted to FDA under proposed § 1150.5 (information provided on certified FDA forms or certified copies of the returns or forms filed with another Federal Agency, such as the Department of Treasury). The yearly class allocation would be based on the methodology USDA currently uses in determining the tobacco product class allocations for the TTPP.

Under the proposed rule, the total assessment (the total amount of user fees for a fiscal year) would be allocated among the six classes of tobacco products based on the units of tobacco products removed into domestic commerce. To make this allocation, FDA would multiply the volume of tobacco products removed for each class by the maximum 2003 Federal excise tax rate for each class to generate a dollar figure for each class of tobacco products. The volume of tobacco products removed would be the ''unit'' that is used for excise tax purposes. For snuff, roll-your-own tobacco, chewing tobacco, and pipe tobacco, the unit would be weight, measured in pounds. For cigarettes and cigars, the unit would be the number of sticks. In making the allocation for a particular fiscal year, we would use data about removals covering the most recent full calendar year. For example, in fiscal year 2014 (beginning October 1, 2013), we would use data about removals occurring during calendar year 2012 (beginning January 1, 2012).

To account for the different excise tax rates for cigars (which differ for small and large cigars), we would do two subcalculations. First, for small cigars, the number of sticks would be multiplied by the maximum 2003 Federal excise tax rate for small cigars to generate a dollar amount for small cigars. Second, for large cigars, the number of sticks would be multiplied by the maximum 2003 Federal excise tax rate for large cigars to generate a dollar amount. The dollar amounts for small and large cigars would be added to generate a dollar figure for the cigar class as a whole. This is consistent with USDA's methodology (Ref. 2, p. 7).

We would use the dollar figures for each of the six classes of tobacco products to calculate the percentages attributable to each class of tobacco products. To arrive at percentages, we

would add the dollar figures for each of the six classes of tobacco products together; this aggregate dollar figure would be the denominator. The dollar figure for each class of tobacco products would be the numerator, and when divided by the aggregate dollar figure, the resulting quotient would be the percentage attributable to that class.

FETRA specifies that tobacco product class allocations must be adjusted periodically to reflect changes in the share of gross domestic volume held by a class of tobacco products, defining ''gross domestic volume'' as the volume of tobacco products removed and not exempt from Federal excise tax (section 625(a)(2) and (c)(2) of FETRA). FETRA does not specify that any changes should be made to tobacco product class allocations to reflect changes in tax rates. Accordingly, USDA does not adjust the tobacco product class allocations to include changes in tax rates. At least one company has questioned the continued use of the 2003 tax rates because those tax rates have changed (75 FR 76921, December 10, 2010). USDA has considered this issue and determined that fluctuations in excise tax rates do not affect class allocations (see *http://www.fsa.usda.gov/Internet/FSA_File/tobacco_determ_11162011.pdf*). FDA is proposing to adopt the same approach because, with respect to the tobacco product class allocations, section 919 of the FD&C Act specifies that, except for reallocations as discussed in the paragraphs that follow, percentages of each class are those determined under FETRA.

Consistent with section 919(b)(2)(B)(iv) of the FD&C Act, the proposed rule also provides that the amount of user fees otherwise assessed to any class of tobacco products not currently regulated under chapter IX of the FD&C Act would be reallocated to the classes of tobacco products that are currently regulated under chapter IX of the FD&C Act. Of the six classes, only the cigar and pipe tobacco classes are not currently regulated under chapter IX and, thus, are not subject to user fees. Under the proposed rule, the user fees that would be assessed to domestic manufacturers and importers of cigars and pipe tobacco would be reallocated to the classes of tobacco products currently subject to chapter IX of the FD&C Act.

FDA is allocating fees among the classes of tobacco products specified in section 919(b)(2)(B)(i) of the FD&C Act. These are the same classes of tobacco products that have been subject to TTPP assessments under FETRA and, as such, the classes for which there is a method for determining the applicable percentages, for class and individual domestic manufacturers and importers within the classes under FETRA. The FETRA percentage is based on gross domestic volume, which is defined as the volume of tobacco products removed within the meaning of the Internal Revenue Code (section 625(a)(2) of FETRA). Under the Internal Revenue Code, the six classes are the only ones defined as ''tobacco products'' that are removed and that are subject to the excise tax requirements (26 U.S.C. 5701 and 5702(c) and (i)). Thus, under the proposed rule, if a tobacco product that is not included in one of the six classes specified in section 919(b)(2)(B)(i) of the FD&C Act is deemed by regulation to be subject to chapter IX of the FD&C Act, fees would not be allocated to such product. If you disagree with this reading, FDA invites comments on what the additional classes would be; how user fee calculations would be made if additional classes were to be added, particularly if added classes were not subject to Federal excise taxes; and support for your view.

2. Individual Domestic Manufacturer or Importer Assessment

As described in the proposed rule (proposed § 1150.9), each quarter we would calculate the assessment imposed on each domestic manufacturer and importer of tobacco products (see section I.A.2 of this document). Information submitted under proposed § 1150.5 would be used along with any other available information in making these calculations. Under the proposed rule, for each class of tobacco products except cigars, we would calculate the domestic manufacturer's or importer's percentage share. This percentage share would be calculated by dividing the Federal excise taxes that the domestic manufacturer or importer paid for the class for the prior quarter by the total excise taxes that all domestic manufacturers and importers in that class paid for the class for that same quarter.[9]

This proposed calculation is the same as that used by USDA for all classes of tobacco products subject to user fees except for cigars. Although USDA uses volume of cigars removed in the preceding quarter to calculate percentage share, 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.'' Thus, if a user fee assessment were to be applied to cigars we would 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 in the cigar class paid for the prior fiscal year. We are requesting comment on this proposed calculation for cigars and have reserved § 1150.9(a)(2) should a user fee assessment be applied to cigars.

The proposed rule also provides that the percentage share would be truncated to the fourth decimal place. Thus, if the percentage share calculated is less than 0.0001 percent, the domestic manufacturer or importer would be excluded from the assessment for that class of tobacco products.

Once the percentage share is calculated, we would then determine the amount of assessment to be collected from a domestic manufacturer or importer each fiscal quarter. FDA would multiply each entity's percentage share by the quarterly assessment for that class of tobacco products (*i.e.*, the total yearly class allocation divided by four). Because the assessments are based on past activity, a domestic manufacturer or importer may be assessed a user fee regardless of whether it removed into domestic commerce any tobacco products during the quarter in which it received an invoice.

3. Annual Adjustment

Proposed § 1150.9(b) provides that annually FDA would make any adjustment to individual domestic manufacturer and importer assessments if needed to account for any corrected assessments and to include those entities that were not assessed in previous quarterly assessments for that fiscal year. The adjustment would help ensure that no domestic manufacturer or importer pays a user fee in excess of its percentage share (section 919(b)(3)(B) of the FD&C Act). FDA intends to use information we have from registrations, along with any other available information, to help ensure that domestic manufacturers and importers are providing the information that would be required under the proposed rule.

E. Notification of Assessments

Proposed § 1150.11 would describe the notification that we would provide each domestic manufacturer and importer of tobacco products. Section

[9] As previously noted, except for cigars, section 919(b)(4) of the FD&C Act requires FDA to determine percentage share for each entity in the same manner described in subsections (e) through (h) of section 625 of FETRA.

919(b)(6) of the FD&C Act requires that FDA notify each domestic manufacturer or importer of tobacco products of the amount of the quarterly assessment imposed no later than 30 days prior to the end of the quarter for which the assessment is made. Consistent with this requirement, the proposed rule would require FDA to notify each domestic manufacturer and importer of tobacco products of the amount of the quarterly assessment imposed on the domestic manufacturer or importer for each quarter of a fiscal year not later than 30 days before the end of the quarter for which the assessment is made. As proposed, the notification would also include information about the allocation of the yearly assessment among each class of tobacco products (Step A) and the percentage share of each class allocated to the domestic manufacturer or importer (Step B).

The notification would also include information on any adjustment FDA made for corrections or any adjustment to include entities that were not assessed in previous quarterly assessments for that fiscal year. In addition, the proposed notification would provide information about how the domestic manufacturer or importer is to pay the user fee and information on accrual of interest if a payment is late. Payment methods currently include check, wire transfer, and online payment. We expect that over time different methods of payment, such as other methods of electronic funds transfer, may develop.

F. Payments

In accordance with section 919(b)(6) of the FD&C Act, proposed § 1150.13 would require that a domestic manufacturer and importer pay an assessment by the last day of the quarter involved. If we have not notified the domestic manufacturer or importer of the amount that is required to be remitted 30 calendar days before the end of a fiscal year quarter, the proposed rule provides that no interest would be assessed until 30 calendar days after the date that we sent notification of the amount owed. Proposed § 1150.13 would also require that payments be submitted in U.S. dollars and in the manner specified in the notification (*e.g.,* check or online payment). As noted, over time the manner of receiving payments may change, such as by check, electronic funds transfer, or online transaction.

Consistent with 31 U.S.C. 3717, the proposed rule also states that interest would begin accruing if payment of the assessment is not made by the last day of the quarter involved. The accrual of interest would begin the next day. For example, if payment is due March 31 but is not received by March 31, then interest would begin to accrue on the unpaid amount on April 1. The proposed rule also explains that if a domestic manufacturer or importer disputes the amount of the assessment, the domestic manufacturer or importer would still be required to pay the assessment by the date due or be subject to interest.

G. Disputes

We are proposing that a domestic manufacturer or importer would be required to submit a dispute in writing regarding an assessment within 45 days of the date of the assessment notification (proposed § 1150.15). If FDA determines there was an error in the amount of the assessment, FDA would refund the amount that was incorrectly assessed. Any subsequent appeals of the dispute would also need to be submitted in writing within 30 days of the date of FDA's response to the dispute. To ensure finality in FDA's accounts and potential refund obligations, we believe it is necessary to have a time limit on disputes over user fee assessments. We believe the proposed timeframes identified are adequate to detect a dispute and prepare a written submission to FDA. The notification of assessment would provide information regarding where to send a dispute and when it needs to be sent. Domestic manufacturers or importers may contact the Center for Tobacco Products (CTP) Ombudsman for further information on dispute options and resolution (*www.fda.gov/CTPOmbudsman*).

H. Penalties

Proposed § 1150.17 would include an explanation that failure to pay a user fee would result in the tobacco product being deemed adulterated under section 902(4) of the FD&C Act. Because a firm would not be able to pay a user fee if it does not submit to FDA the information the Agency needs to be able to calculate the amount of fees assessed to such firm, under the proposed rule failure to submit such information would also result in the tobacco product being deemed adulterated. An adulterated tobacco product is subject to enforcement action by FDA, including injunction, seizure, and civil money penalties (sections 302, 303, and 304 of the FD&C Act (21 U.S.C. 332, 333, and 334)). The failure to submit information that is required so FDA can calculate assessments and fees owed—to help assure the product is not adulterated—would also be a violation of section 909 of the FD&C Act (21 U.S.C. 387i), and the failure to make a report required by section 909 is a prohibited act under section 301 of the FD&C Act (21 U.S.C 331). The proposed rule also explains that any person who knowingly fails to provide required information or provides false information may be subject to the criminal penalties prescribed in 18 U.S.C. 1001.

III. Effective Date

FDA proposes that any final rule that issues based on this proposal become effective 30 days after the final rule publishes in the **Federal Register**.

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) 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. 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 proposed 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 proposed rule 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

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 proposed rule is not a significant regulatory action as defined by 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 proposed 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 $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Baseline

Section 919 of the FD&C Act establishes a system of collecting user fees, starting from the enactment of the Tobacco Control Act on June 22, 2009. This general system for collecting user fees has already been implemented and has been operational for more than 2 years.

In order to bill user fees, FDA must have data on the domestic manufacturers and importers required to pay. Currently, the necessary information is provided by USDA through a Memorandum of Understanding (Ref. 1). Section 919(b)(7)(B) of the FD&C Act requires the Secretary, starting no later than fiscal year 2015, to ensure that FDA is able to determine the yearly class allocations and the shares of each domestic manufacturer and importer within each class. This rule, when finalized, would provide a mechanism for obtaining the information necessary for these user fee calculations. Without this proposed rule, the Agency would have to gather the information in some other way. Our forecast of the method by which FDA would obtain this information in the absence of rulemaking provides the baseline for this proposed rule. While it is difficult to determine exactly how this would be done without a regulation establishing the process, section 919(b)(7)(B) of the FD&C Act would be implemented in some way and FDA would continue to collect user fees. It is important to note that without a regulation in place, implementation of the user fee provision might require new legislation, without which there would be potentially severe difficulties.

Methods for FDA to ensure that it can obtain the information needed to calculate or collect user fees starting in fiscal year 2015 could include obtaining the information from a Federal Agency (or Agencies) other than USDA or forming an agreement under which USDA continues to collect this information as they currently do, even though USDA will not need the information after fiscal year 2014. Either of these options might require new legislation to implement. Another possibility is for Congress to pass legislation explicitly requiring firms to submit the requisite information but without the need for an implementing regulation. We assume that in the absence of regulation, FDA would most likely obtain the information from Federal Agencies other than USDA, and we use this as our primary baseline. This provides the greatest contrast to the proposed rule from the perspective of regulated industry. We also discuss how the proposed rule would compare to the other possible baseline scenarios.

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. FDA could obtain raw data with which to calculate user fees, or another Agency could compile the information, perform the calculations, and possibly even issue user fee bills on behalf of FDA; in either case, government Agencies would compile the information from existing sources. The form currently used by USDA requests information from forms submitted to the TTB and CBP. Therefore, agreements between multiple agencies would likely have to be put into place because it is not clear that either TTB or CBP has all of the necessary information. The government (whether FDA or another Agency) would bear the costs of compiling all of the information from the various TTB and CBP forms. The difficulty of this task depends on the current format of the information and the amount of work that would be required to put it into a format that can be used by FDA. Because of statutes governing TTB and CBP, without additional legislation, this system could limit FDA's ability to disclose information supplied by another Agency when taking enforcement action or even when sending bills.

C. Number of Affected Entities

This proposed rule would apply to all entities that manufacture or import any tobacco product that is regulated under the FD&C Act and belongs to one of the classes of tobacco products listed in section 919 of the FD&C Act. Currently, manufacturers and importers of cigarettes, snuff, chewing tobacco, and roll-your-own tobacco fit these criteria. Based on discussions with another Federal Agency, FDA estimates that 200 such entities would be affected by this proposed rule.

D. Impact of the Proposed Rule

Under the proposed rule, manufacturers and importers would have to submit information to FDA on a monthly basis, whereas under the primary baseline they would not have to submit any information to FDA. Although FDA is proposing an information collection very similar to that currently conducted by USDA, there would be some private sector costs associated with the transition from USDA to FDA collection. Manufacturers and importers would need to read the regulation or any notification potentially sent to them to explain the transition. They would need to switch forms and update the address for submission. To the extent that the form changes,[10] they would have to learn how to use the new form. FDA estimates that this transition would take 3 hours per manufacturer or importer. Valuing time at the average tobacco manufacturing industry wage of $25.27 [11] per hour, doubled to $50.54 per hour to account for benefits and overhead, this transition cost would be $151.62 per manufacturer or importer. Table 1 shows that the total transition cost would be approximately $30,000.

TABLE 1—PRIVATE SECTOR TRANSITION COST

No. of entities	200
No. of hours	3

[10] The current draft FDA form is very similar to the USDA form.

[11] May 2011 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200—Tobacco Manufacturing. *http://www.bls.gov/oes/*

TABLE 1—PRIVATE SECTOR TRANSITION COST—Continued

Cost ($)	30,324

All of the entities affected by this proposed rule would be required on a monthly basis to submit the proposed FDA form containing certain identifying information, the number of units introduced into domestic commerce [12] in the prior month, and excise taxes paid for such introduction into domestic commerce, by tobacco product class. This form is estimated to take 3 hours to complete. In addition, each entity would be required on a monthly basis to submit certified copies of the returns and forms that relate to the introduction of tobacco products into domestic commerce and the payment of Federal excise taxes imposed. Submitting copies of these forms is estimated to take 1 hour each month. These submissions are required even if the quantity introduced into domestic commerce during the month in question is 0. We do not consider any time cost associated with remitting payment for user fees (or the distributional effect of the aggregate amount of the user fees shifted from tobacco manufacturers and importers to government) because user fees will be assessed and paid regardless of how section 919(b)(7)(B) of the FD&C Act is implemented. Similarly, we do not consider the time cost of disputing or appealing user fee assessments because similar mechanisms would be in place regardless of how section 919(b)(7)(B) is implemented.

Table 2 shows the annual private sector costs of complying with this proposed rule, compared with the primary baseline, would be approximately $485,000.

TABLE 2—ANNUAL PRIVATE SECTOR COMPLIANCE COST

FDA form:	
No. of entities	200
Annual submissions	12
Hours per submission	3
Cost ($)	363,888
Copies of other forms:	
No. of entities	200
Annual submissions	12
Hours per submission	1
Cost ($)	121,296
Total Cost ($)	485,184

Under the primary baseline, government workers (at FDA or another Agency) would do the work of compiling the information contained in various TTB and CBP forms that is needed to calculate and bill user fees. Therefore, government costs would decrease with this proposed rule in an amount that would approximately offset the private sector costs discussed previously. Government setup costs for learning how to compile the necessary data from the various relevant forms would be reduced or eliminated, partly offsetting the private sector transition cost. In addition, government costs for actually compiling this information on an ongoing basis would be eliminated. If the government is not able to perform these functions as efficiently as manufacturers and importers, the reduction in government costs would exceed the increase in private compliance costs, resulting in a net benefit to society. If government is able to perform these functions more efficiently, the increase in private costs would exceed the reduction in government costs, resulting in a net cost to society. Therefore, requiring industry to compile this information and submit it to FDA could result in either a net societal cost or benefit, the size of which is expected to be very small.

This proposed rule would have other impacts. It would allow FDA to be in control of the information used for calculating and billing user fees. This would be beneficial for resolving disputes and taking enforcement action if a firm fails to pay. By contrast, under the baseline (in which FDA obtains information from Federal Agencies other than USDA), taking enforcement action or even billing for user fees could be more challenging without additional legislation. In addition, because FDA would not have to rely on cooperation from another Agency, this proposed rule would likely result in greater efficiency. Under the primary baseline, the possibility would exist that at some time in the future the other Agencies would no longer be willing or able to provide the necessary data. FDA would then face the same question it faces today as to how to ensure that it can obtain the relevant data. Therefore, compared with the primary baseline, this proposed 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 would without legislation.

E. Alternative Baselines

The primary baseline assumes that starting in fiscal year 2015, FDA would obtain the information necessary for collecting user fees directly from another Federal Agency (or Agencies) other than USDA. However, there are other ways that FDA might obtain the necessary data.

Under one alternative baseline, USDA would continue to collect the information and perform market share calculations as it does today. Compared with this baseline scenario, the only industry cost of this proposed rule would be the cost of the transition. This would be a social cost (there would be no offsetting cost reduction) because if USDA were to continue to collect the information as it does today, there would be no learning or transition cost for government or industry. Because industry would be responsible for compiling and submitting the necessary information under either this baseline or the proposed rule, there would be no ongoing incremental cost to industry or to society as a whole. However, because USDA's program sunsets after fiscal year 2014, it is not clear that they could continue to collect this information without new legislation. Therefore, the proposed rule would eliminate the potential need for new legislation or the potentially severe problems that would be faced without new legislation. Finally, if the information is collected for FDA's sole use, it would arguably be more efficient over the long run for FDA to collect the information itself. Combining the information collection and use in one Agency would yield some societal benefit in the form of cost savings.

Under another possible baseline, Congress could pass legislation explicitly requiring firms to submit the information we propose to collect in this rule without the need for issuing an implementing regulation. In terms of the mechanics of the process (the transition of the information collection to FDA and the ongoing need for industry to compile and submit the data), the proposed rule would have no effect under this scenario. However, issuance of this rule would make such legislation unnecessary.

F. Impact on Small Entities

1. Numbers Affected

Under the primary baseline, this proposed rule would impose costs on domestic tobacco product manufacturers and importers. U.S. Census data provide some insight into the proportion of such entities that may be small. All cigarette manufacturers would be affected by this rule, while an unknown proportion of other tobacco product manufacturers would be affected. Importers are not identified in the Census, but instead may be designated as wholesalers or retailers. Most tobacco product-importing

[12] The technical term for this is ''removal,'' which is defined in footnote 2.

wholesalers would be classified as ''tobacco and tobacco product merchant wholesalers.'' Although many different categories of retailers (such as grocery and convenience stores) may sell tobacco products, those most likely to import them are specialty tobacco shops and non-store retailers operating electronically or through delivery services. Table 3 shows the Small Business Administration (SBA) size thresholds for small businesses in each of these categories, as well as the most comparable size categories available from the U.S. Census (Refs. 4, 5, and 6).[13] For cigarette manufacturers and tobacco product retailers, the proportion found to be small will be underestimated because the Census size category is lower than the SBA threshold.

TABLE 3—SBA SIZE STANDARDS AND CENSUS SIZE CATEGORIES FOR TOBACCO PRODUCT MANUFACTURERS AND IMPORTERS

	NAICS	Description of NAICS category	SBA Size Standard (employees or $million)	Census size category (employees or $million)
Tobacco Product Manufacturers:				
	312221	Cigarette Manufacturing	1,000	500
	312229	Other Tobacco Product Manufacturing	500	500
Potential Tobacco Product Importers:				
Wholesalers	424940	Tobacco and Tobacco Product Merchant Wholesalers.	100	100
Retailers	453991	Tobacco Stores	$7.0	$5.00
	454111	Electronic Shopping	$30.0	$25.00
	454113	Mail-Order Houses	$35.5	$25.00

Table 4 shows the number of businesses with employees in each of the categories described previously, the number qualifying as small according to the Census size standard, and the percent qualifying as small. Statistics of U.S. Businesses data from 2008 indicate 79 percent of cigarette manufacturing and 89 percent of other tobacco product manufacturing businesses with employees are small (Ref. 5). These data also show that 91 percent of ''tobacco and tobacco product merchant wholesalers'' qualify as small. Data from the 2007 Economic Census show that 94 percent of tobacco shops with payroll are small, while 98 percent of ''electronic shopping'' and 94 percent of ''mail-order'' retailers are small (Ref. 6). We do not know what proportion of affected entities would fall into each of these categories, but based on the percentages found in Table 4 and the small number of manufacturing firms relative to the total number expected to be affected by this proposed rule (200), it is likely that about 90 percent of the affected entities would be small. This implies that approximately 180 (0.9×200) small entities would be affected.

TABLE 4—ESTIMATED PERCENTAGE OF SMALL FIRMS AMONG FIRMS WITH EMPLOYEES

NAICS	Description of NAICS category	Number of firms	Number of firms below census size standard	Percentage of small firms (%)
312221	Cigarette Manufacturing	19	15	79
312229	Other Tobacco Product Manufacturing	44	39	89
424940	Tobacco and Tobacco Product Merchant Wholesalers.	1,118	1,019	91
453991	Tobacco Stores	4,025	3,793	94
454111	Electronic Shopping	11,646	11,374	98
454113	Mail-Order Houses	5,645	5,281	94

2. Costs for Small Entities

Table 5 shows the potential effect of this rule on small tobacco product manufacturers. Compliance costs are compared to average value of shipments, determined for establishments based on 2002 Census data (Ref. 7). We assume that most small manufacturers operate a single establishment. We use 2002 data rather than 2007 data because 2007 data suppress most information about value of shipments by tobacco product establishment size in order to safeguard confidentiality. The distribution of small tobacco product manufacturing establishments by employment size and the average value of shipments by employment size may have changed since 2002. Therefore, we are uncertain whether the effect of this proposed rule would be the same today as estimated in table 5. With that caveat in mind, we see that the annual compliance cost equals 0.71 percent of average value of shipments for other tobacco product manufacturing establishments with 1 to 4 employees, which could be a substantial portion of profits. There were 38 such other tobacco product manufacturing establishments in 2002, but we do not have enough information to determine how many manufactured cigarettes, snuff, chewing tobacco, or roll-your-own tobacco and would therefore be affected by the proposed rule. Therefore, we are unable to rule out the possibility that this proposed rule would have a significant economic

[13] Tobacco product manufacturers (and importers) are considered small under the FD&C Act if they employ fewer than 350 people. This definition is used in determining the deadline for compliance with certain requirements under the FD&C Act. However, the SBA's definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

impact on a substantial number of small entities.

TABLE 5—POTENTIAL IMPACT ON TOBACCO PRODUCT MANUFACTURERS (BY SIZE)

Type of manufacturing establishment	Average value of shipments (million $)	Annual compliance cost as a percent of average value of shipments	Transition cost as a percent of average value of shipments
Cigarette (All)	2,304	0.00	0.00
Other Tobacco Product (All)	44	0.01	0.00
1 to 4 employees	0.3	0.71	0.04
5 to 9 employees	2	0.16	0.01
10 to 19 employees	4	0.06	0.00
20 to 49 employees	12	0.02	0.00
50 to 99 employees	17	0.01	0.00
100 to 249 employees	64	0.00	0.00
250 to 499 employees	273	0.00	0.00

3. Regulatory Relief

An alternative that might reduce costs for small entities 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. A drawback to this approach is that FDA would be unable to distinguish a firm that failed to report from a firm that introduced zero units into domestic commerce in a particular month.

G. Conclusion

Compared with the primary baseline, this proposed rule would 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 proposed rule would also allow FDA to be in control of the data needed for calculating and billing user fees and would resolve impediments that may otherwise exist to FDA's ability to use the data for its intended purpose. Compared with other possible baseline scenarios, this proposed 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.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). A description of these provisions is given in the paragraphs that follow 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. FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 proposed rule would require 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 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 proposed 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, the proposed rule would require 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 tobacco products.

TABLE 6—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 (Identifying information, fee amount, etc. (quarterly)	100	4	400	1	400
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					10,020

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

Table 6 describes the annual reporting burden of 10,020 hours as a result of the provisions set forth in this proposed 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 fees each fiscal quarter. Based on our experience with the assessment of user fees for other FDA-regulated products, we estimate that approximately 1 percent might appeal an assessment.

For proposed § 1150.5(a), (b)(1), and (b)(2), FDA estimates that 200 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 (200 respondents × 12 months × 3 hours). For proposed § 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 (200 respondents × 12 months × 1 hour per response).

For proposed § 1150.13, FDA estimates that 100 domestic manufacturers and importers will be submitting user fees on a quarterly basis. Therefore, the number of burden hours for this section is 400 hours (100 respondents × 4 times per year submission × 1 hour per response). FDA estimates that approximately 1 percent of those respondents assessed user fees will dispute the amounts under proposed § 1150.15(a), for a total amount of 10 hours (100 respondents × 0.01 × 1 dispute submission × 10 hours per response.) FDA also estimates that of those who dispute their user fees, one will ask for further review by FDA under proposed § 1150.15(d), for a total amount of 10 hours (1 dispute submission × 10 hours per response.) Total burden hours for this rule are 10,020 hours (7,200 + 2,400 + 400 + 10 + 10).

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments regarding the proposed information collection to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submissions@omb.eop.gov.*

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would 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 tentatively concludes that the proposed 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. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

X. 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 addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register.**)

1. Memorandum of Understanding on the Sharing of Tobacco Market Share Information Between the Food and Drug Administration, U.S. Department of Health and Human Services and the Commodity Credit Corporation and Farm Service Agency, U.S. Department of Agriculture, August 2009.
2. U.S. Department of Agriculture, ''Determination of the Administrator of the Farm Service Agency and Executive Vice President of the Commodity Credit Corporation Regarding the Current 'Step A' and 'Step B' Assessment Methods in the Tobacco Transition Payment Program,'' *http://www.fsa.usda.gov/Internet/FSA_File/tobacco_determ_11162011.pdf*).
3. U.S. Department of Agriculture, Commodity Credit Corporation, Form

CCC–974, ''Report of Tobacco Product Removals Subject to Tax for the Tobacco Transition Assessment Program (TTAP).''
4. U.S. Small Business Administration, 2010, Table of Size Standards. *http://www.sba.gov/content/table-small-business-size-standards,* accessed July 2011.
5. U.S. Census Bureau, Statistics of U.S. Businesses (SUSB), Latest SUSB Annual Data, U.S., All Industries, 2008, *http://www.census.gov/econ/susb/accessed* July 2011.
6. U.S. Census Bureau, American FactFinder, Establishment and Firm Size: Summary Statistics by Sales Size of Firms for the United States: 2007, 2007 Economic Census, Retail Trade, Subject Series, *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_44SSSZ4&prodType=table.*
7. U.S. Census Bureau, American FactFinder, ''2002 Economic Census, Manufacturing: Industry Series: Industry Statistics by Employment Size: 2002,'' *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2002_US_31I4&prodType=table.*
8. Draft 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, it is proposed that chapter I of title 21 be amended by adding part 1150 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 and 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 and cigars, or

(2) The weight (measured in pounds) for snuff, chewing tobacco, pipe 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. 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 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) Its Tobacco Tax and Trade Bureau (TTB) Permit Number(s);

(v) Its Employer Identification Number(s) (EIN); and

(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) 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 figure).

(2) For cigars, FDA will calculate the percentage share as follows:

(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 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 figure).

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

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

(4) FDA will divide the class figure by the total 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 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) [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 and then 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) An entity must submit in writing any dispute regarding an assessment within 45 days of the date on the assessment notification.

(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 must be submitted in writing within 30 days from the date on FDA's response.

§ 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: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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