

Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products (Revised)*

Guidance for Industry Small Entity Compliance Guide

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <http://www.regulations.gov>. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with Docket No. FDA-2014-D-0917.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m.

Additional copies are available online at <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to Food and Drug Administration, Center for Tobacco Products, Document Control Center, ATTN: Office of Small Business Assistance, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products**

May 2016

*** This is a revision to the first edition of this guidance, which was issued in July 2014. Revisions are noted by date at the end of the guidance.**

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

Guidance for Industry¹ Small Entity Compliance Guide

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to help small businesses understand and comply with FDA's requirements for the submission of information needed to calculate the amount of user fees owed by each domestic manufacturer or importer of tobacco products under section 919 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, and roll-your-own tobacco are currently required to submit the information to FDA. Domestic manufacturers and importers of cigars and pipe tobacco must begin submitting the information to FDA by the 20th day of August, 2016. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance was prepared by the Office of Management and the Office of Regulations in the Center for Tobacco Products at FDA.

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II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009 (Public Law 111-31), amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Included in the Tobacco Control Act is the requirement that FDA assess and collect user fees.

Section 919(a) of the FD&C Act requires FDA to, in accordance with that section, “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). Under the calculations required by section 919 of the FD&C Act, the tobacco products that are subject to user fee assessments are cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco. 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 one-fourth of that total each quarter of the fiscal year. The FD&C Act provides for the total quarterly assessment to be allocated among classes of tobacco products. The class allocation is based on each tobacco product class’ volume of tobacco products removed² into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its market share for that tobacco product class.

In the *Federal Register* of May 31, 2013 (78 FR 32581), FDA issued a notice of proposed rulemaking (NPRM) to add 21 CFR part 1150 to require domestic tobacco product manufacturers and importers to submit to FDA information needed to calculate the amount of user fees to assess each domestic manufacturer and importer under the FD&C Act. In the *Federal Register* of July 10, 2014 (79 FR 39302), FDA finalized portions of the User Fee proposed rule related to cigarettes, snuff, chewing tobacco, and roll-your-own tobacco, which is codified at 21 CFR part 1150. FDA did not finalize portions of the proposed rule relating to cigars and pipe tobacco because those product classes were not subject to FDA’s authority at the time. In the *Federal Register*, FDA published the final rule, “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act” (Deeming Rule), which brought cigars and pipe tobacco under FDA’s FD&C Act authority and, among other things, the user fee requirements of section 919. In accordance with this new Deeming Rule authority, FDA finalized the remaining portions of the User Fee rule related to cigars and pipe tobacco in the *Federal Register*, amending 21 CFR part 1150 to include requirements for domestic manufacturers and importers of cigars and pipe tobacco.

III. QUESTIONS AND ANSWERS

A. Who must submit information to FDA?

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.”

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The final rules apply to domestic manufacturers and importers of six classes of tobacco products: cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco.

B. What information must be submitted to FDA by domestic tobacco product manufacturers and importers?

Each domestic manufacturer and importer must submit the following information and documents to FDA:

- Its name and the mailing address of its principal place of business;
- The name and a telephone number, including area code, of an office or individual that FDA may contact for further information;
- The email address and postal address for receipt of FDA notifications;
- Its Alcohol and Tobacco Tax and Trade Bureau (TTB) Permit Number(s);
- Its Employer Identification Number(s) (EIN);
- For each TTB tobacco permit:
 - The units of product (i.e., number of sticks for cigarettes and pounds for other tobacco products), by class, removed and not tax exempt for the prior month and
 - The Federal excise tax paid, by class, for such removal;
- 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;
- Certified copies of the returns and forms that relate to:
 - The removal of tobacco products into domestic commerce (as defined by section 5702 of the Internal Revenue Code of 1986); and
 - The payment of the Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986.

(§ 1150.5(b))

This information is currently submitted on TTB Forms 5210.5, 5000.24, and 5220.6 and Customs CBP Form 7501.

Each domestic manufacturer and importer of cigars must provide additional data as part of the first report required under this rule. Because section 919(b)(5) of the FD&C Act requires FDA to allocate user fees to individual manufacturers and importers of cigars based upon the total amount of excise taxes that each cigar firm paid in the prior fiscal year, the rule requires that cigar firms report the information above for each prior month in the fiscal year as part of the first monthly report of data under this rule. After this first report, domestic manufacturers and importers of cigars must report data for the prior month, like manufacturers and importers of the other classes of tobacco products are required to do.

(§ 1150.5(c))

C. When must this information be received by FDA?

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- For cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco, this information must be received by FDA by the 20th of each month.
- Cigar and pipe tobacco companies must begin submitting this information by the 20th day of August, 2016.

The information must be submitted on a monthly basis, even in months when no tobacco product is removed into domestic commerce. (See § 1150.5(a).)

D. How must this information be submitted to FDA?

Domestic manufacturers and importers must use Form FDA 3852 and attach copies of the appropriate supporting TTB and CBP forms (currently TTB Forms 5210.5, 5000.24, and 5220.6 and CBP Form 7501). This form is available online and in paper form. (See § 1150.5.)

Submit Form FDA 3852 and supporting documents to FDA by mail:

Food and Drug Administration,
Center for Tobacco Products,
Document Control Center,
ATTN: OM, Division of Financial Management, User Fee Team
Building 71, Room G335
10903 New Hampshire Avenue,
Silver Spring, MD 20993-0002

electronically: TOBACCOUSERFEES@fda.hhs.gov, or

by fax: 301-595-1429 or 301-595-1430.

E. How will FDA allocate the total assessment among the classes of tobacco products for each quarter of a fiscal year?

FDA will calculate the percentage shares for each class as follows:

- FDA will multiply the units of product removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for that applicable class or subclass (class dollar figure). The cigar class percentage share will be the sum of this calculation for the small and large cigar subclasses.
- FDA will total the class dollar figures for all tobacco classes for the most recent full calendar year (total dollar figure).
- FDA will divide the class dollar figure by the total dollar figure to determine the percentage share for each class.
- FDA will calculate the allocation for each class of tobacco products by multiplying the percentage share for each class by the total assessment.

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- FDA will reallocate the percentage share of any class of tobacco products that has not, by the beginning of the fiscal year, been deemed subject to chapter IX of the FD&C Act.

(§ 1150.7(a))

Because FDA can perform class allocations only on a full fiscal year basis, the percentage share for the cigar and pipe tobacco classes will be reallocated to the other tobacco product classes until October 1 of the first full fiscal year following the effective date of this rule.

F. How will FDA calculate the assessment owed by each domestic manufacturer or importer for each quarter?

The assessment for each class of tobacco products is allocated 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.

- For the cigarette, snuff, chewing tobacco, roll-your-own tobacco, and pipe tobacco classes, 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.
- For the cigar class, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior fiscal year by the total excise taxes that all domestic manufacturer and importers paid for the class for the same fiscal year.

If the percentage share calculated for a domestic manufacturer or importer is less than 0.0001 percent, the manufacturer or importer does not have to pay an assessment. Within each class of tobacco products, the assessment owed by a domestic manufacturer or importer for the quarter is the quarterly class allocation multiplied by the domestic manufacturer's or importer's percentage share for that class of tobacco products. (See § 1150.9(a).)

G. Will FDA make adjustments to individual domestic manufacturer or importer assessments?

Yes. Annually, FDA will make any necessary adjustments to individual domestic manufacturer or importer assessments if needed to account for any corrections (e.g., to include domestic manufacturers or importers that were not included in a relevant assessment calculation) (§ 1150.9(b)).

H. When will FDA notify each domestic manufacturer and importer of the amount of the quarterly assessment?

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FDA will notify each domestic manufacturer and importer of the amount of the quarterly assessment no later than 30 calendar days before the end of each fiscal year quarter (§ 1150.11(a)).

I. What information will be included in the notification from FDA?

The notification sent to each domestic manufacturer and importer will include the following:

- The amount of the quarterly assessment and the date that payment of the assessment must be received by FDA;
- Class assessment information;
- Domestic manufacturer or importer assessment information;
- Any adjustments FDA has made under § 1150.9(b);
- The manner in which assessments are to be remitted to FDA;
- Information about the accrual of interest if a payment is late; and
- Information regarding where to send a dispute and when it needs to be sent.

(§ 1150.11(b))

J. When and how must payment of assessments be submitted to FDA?

Payment of an assessment must be received by FDA no later than the last day of each fiscal year quarter. In the event that FDA does not notify a domestic manufacturer or importer of the amount of the quarterly assessment at least 30 days before the end of the calendar year, payment of that assessment must be received by FDA no later than 30 days after such notification. The payment must be in U.S. dollars and submitted to FDA in the manner specified in the notification. (See § 1150.13.)

K. Can a domestic manufacturer or importer dispute an FDA assessment?

Yes, a domestic manufacturer or importer can dispute an FDA assessment but must still pay the assessment (§ 1150.13(e)). Section 1150.15 outlines the dispute process.

L. What is the penalty for failure to pay an assessed user fee?

A tobacco product is deemed adulterated under section 902(4) of the FD&C Act (21 U.S.C. 387b(4)) if the domestic manufacturer or importer fails to pay a user fee by the later of the following: 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 about the amount of the fee. (§ 1150.17(a))

M. What are the penalties for failure to report the information required by § 1150.5?

A tobacco product is deemed adulterated under section 902(4) of the FD&C Act if the domestic manufacturer or importer fails to report the information required by § 1150.5 to calculate assessments. Failure to report the information is also a prohibited act under section 301(e) of the FD&C Act (21 U.S.C. 331(e)). (See § 1150.17(b)-(c).)

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N. Are there penalties related to the submission of false information under § 1150.5?

Yes. Information submitted under § 1150.5 is subject to 18 U.S.C. 1001 and other appropriate civil and criminal statutes (§ 1150.17(d)).

O. When do these rules become effective?

The first user fee rule became effective for domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, and roll-your-own tobacco on August 11, 2014. The new user fee rule will become effective for the cigars and pipe tobacco classes 90 days after the rule published in the *Federal Register*. However, as explained in section III.C, the first submission of required information will be due by the 20th day of August 2016 for cigars and pipe tobacco.

P. Will FDA provide assistance for small businesses seeking additional information about this rule?

FDA's Center for Tobacco Products has established an Office of Small Business Assistance in an effort to help small businesses access up-to-date information and comply with the requirements of the Tobacco Control Act. CTP's Office of Small Business Assistance can be reached at SmallBiz.Tobacco@fda.hhs.gov or at 1-877-CTP-1373 (1-877-287-1373), Monday-Friday, 9:00 a.m. – 4:00 p.m.

Document History:

- July 2014 – First edition of guidance was issued.
- May 2016 – Guidance was updated to address amendments to 21 CFR part 1150 that include requirements for domestic manufacturers and importers of cigars and pipe tobacco. Guidance was also updated to include a new title format, a new Internet address, and minor editorial changes.