(3) This paragraph (b) applies to a retailer only if that retailer is responsible for or directs the warning statements required under the paragraph. However, this paragraph does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health warning that has been altered by the retailer in a way that is material to the requirements of this section.

(c) *Marketing requirements.* (1) Except for cigars sold individually and not in a product package, the warning statements required for packages in paragraph (a)(1) of this section must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(2) The warning statements required for advertisements in paragraph (a)(1) of this section must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(3) Each person required to randomly display and distribute or rotate warnings in accordance with an FDA-approved plan under this part shall submit a proposed warning plan to FDA no later than either 12 months after May 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later.

§ 1143.7 Language requirements for required warning statements.

The text in each warning statement required in § 1143.3 or § 1143.5 must be in the English language, except as follows:

(a) In the case of an advertisement that appears in a non-English medium, the text in the required warning statement must appear in the predominant language of the medium whether or not the advertisement is in English, and;

(b) In the case of an advertisement that appears in an English language medium but that is not in English, the text in the required warning statement must appear in the same language as that principally used in the advertisement.

§ 1143.9 Irremovable or permanent required warning statements.

The warning statements required by this section must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a product label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1143.11 Does not apply to foreign distribution.

The provisions of this part do not apply to a manufacturer or distributor of tobacco products that does not manufacture, package, or import tobacco products for sale or distribution within the United States.

§ 1143.13 Effective date.

(a) Except as stated in paragraph (b) of this section, this part will take effect 24 months after May 10, 2016. The effective date will be with respect to the date of manufacture, provided that, in any case, beginning 30 days after the effective date, a manufacturer may not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with this part.

(b) The requirement to submit a warning plan to FDA under § 1143.5(c)(3) will take effect 12 months after May 10, 2016.

PART 1150—USER FEES

Sec.

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

SOURCE: 79 FR 39310, July 10, 2014, unless otherwise noted.

§ 1150.1 Scope.

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

§ 1150.3 Definitions.

The following definitions are applicable to this part:

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

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

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

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

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

Units of product means:

(1) The number of sticks for cigarettes, or

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

Units of product 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.

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

[79 FR 39310, July 10, 2014, as amended at 81 FR 28715, May 10, 2016]

§ 1150.5 Required information.

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

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

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

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

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

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

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

(2) *Removal information.* The units of product, by class, removed and not tax exempt for the prior month and the

Federal excise tax it paid, by class, for such removal.

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

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

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

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

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

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

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

[79 FR 39310, July 10, 2014, as amended at 81 FR 28715, May 10, 2016]

§ 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 dollar figure).

(2) For cigars, FDA will:

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

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

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

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

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

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

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

[79 FR 39310, July 10, 2014, as amended at 81 FR 28716, May 10, 2016]

§ 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) For the cigar class, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior

fiscal year by the total excise taxes that all domestic manufacturers and importers paid for the class for the prior fiscal year.

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

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

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

[79 FR 39310, July 10, 2014, as amended at 81 FR 28716, May 10, 2016]

§ 1150.11 Notification of assessments.

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

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

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

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

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

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

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

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

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

§ 1150.13 Payment of assessments.

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

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

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

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

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

§ 1150.15 Disputes.

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

(1) Submitted in writing;

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

(3) Legible and in English; and

(4) Sent to the address found on our website (*https://www.fda.gov/tobaccoproducts/manufacturing/tobacco-user-fees*).

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

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

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

[79 FR 39310, July 10, 2014, as amended at 89 FR 13980, Feb. 26, 2024]

§ 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.