21 CFR PART 1150 USER FEES – SUBMISSION OF DATA NEEDED TO CALCULATE USER FEES FOR DOMESTIC MANUFACTURERS AND IMPORTERS OF TOBACCO PRODUCTS

Presented by
Krystal Monaco
Office of Management, CTP, FDA

Kristina Peters
Regulatory Officer
Office of Compliance and Enforcement, CTP, FDA

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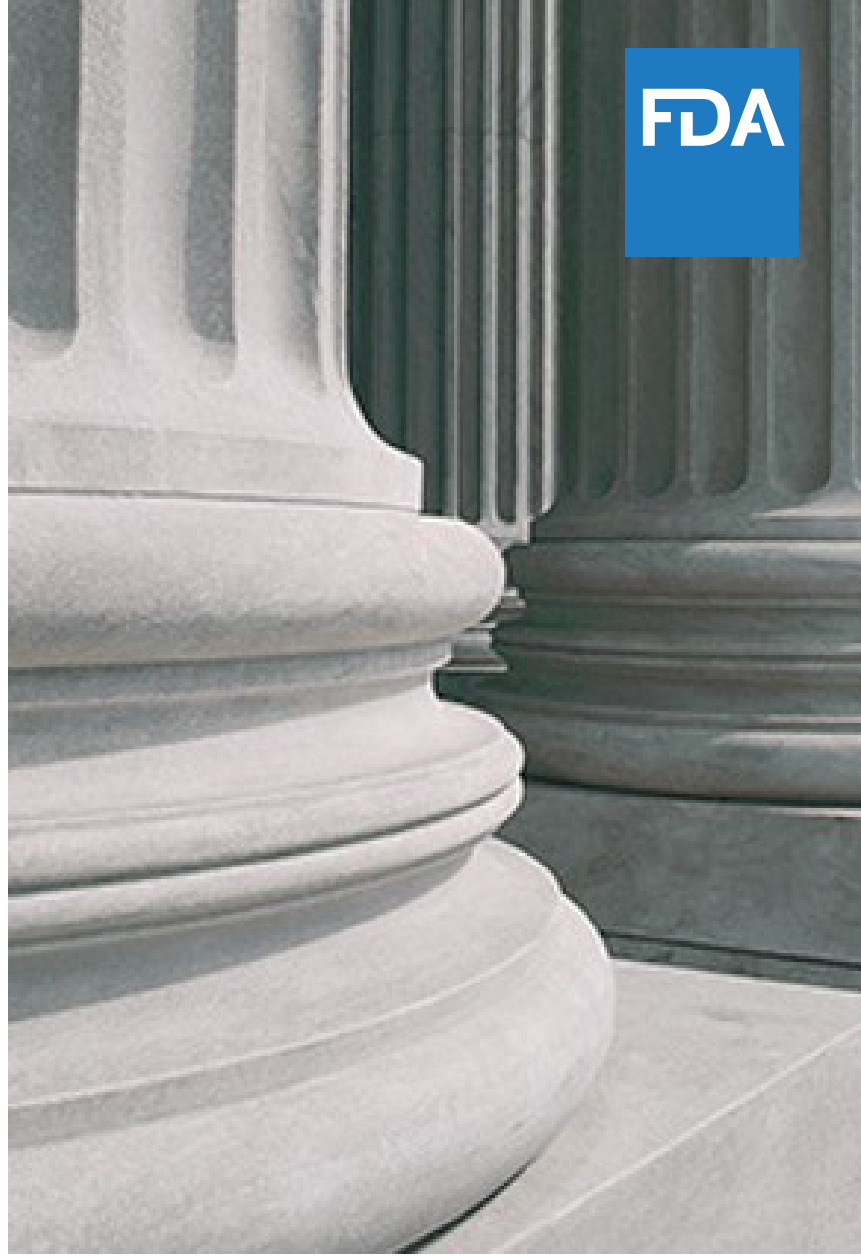

AGENDA

- FDA's user fee authority
- Classes of tobacco products subject to user fees assessments
- Definitions
- What information to submit
- When to submit required information
- How to submit the required information
- FDA's user fee process
- Payment Agreement
- Helpful Information

USER FEE AUTHORITY

Section 919(a) of the Federal Food, Drug, and Cosmetic Act (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).

21 CFR Part 1150 requires domestic tobacco product manufacturers and importers to submit information that FDA needs to calculate the user fees for each domestic manufacturer and importer.

CLASSES OF TOBACCO PRODUCTS SUBJECT TO USER FEE ASSESSMENTS

Domestic manufacturers and importers of the following classes of tobacco products are subject to user fees:

- Cigarettes
- Snuff
- Chewing Tobacco
- Roll-Your-Own Tobacco
- Cigars
- Pipe Tobacco

DEFINITIONS

Domestic Manufacturer

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.

Importer

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.

WHAT INFORMATION TO SUBMIT

Each domestic manufacturer and importer of tobacco products must submit the following information:

1. Identification Information
2. Removal Information
3. Certified Copies

IDENTIFICATION INFORMATION

- The company name and mailing address of its principal place of business
- A contact name and phone number
- BOTH an active email address AND postal address to which FDA can send notifications
- The Employer Identification Number(s) (EIN)
- The Alcohol and Tobacco Tax and Trade Bureau (TTB) Permit Number(s)

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.

- **Must be reported for *each* TTB tobacco permit.**
- **Must be reported even if *zero* tobacco products were removed.**

"removed"

Removal of tobacco products from the factory or from internal revenue bond under 26 U.S.C. 5704, as the Secretary 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.

"units of product"

Cigars, Cigarettes: number of sticks

Pipe Tobacco, Snuff, Chewing Tobacco, and Roll-Your-Own Tobacco: weight in pounds

"not tax exempt"

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.

CERTIFIED COPIES

- Certified copies of the returns and forms that relate to:
  - The removal of tobacco products into domestic commerce, AND
  - The amount of Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986

WHEN TO SUBMIT THE REQUIRED INFORMATION

- Each domestic manufacturer and importer must submit the required information every month
- FDA must receive the required information **no later than the 20th day of each month**

HOW TO SUBMIT THE REQUIRED INFORMATION

- Domestic manufacturers and importers must use **Form FDA 3852** and attach copies of the appropriate supporting TTB and CBP forms.
- Current supporting forms may include TTB Forms 5210.5, 5000.24, and 5220.6 and CBP Form 7501
- Form FDA 3852 is available online and in paper form.
  http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM406546.pdf

HOW TO SUBMIT THE REQUIRED INFORMATION

Submit Form FDA 3852 and supporting documents to FDA:

Electronically:
TOBACCOUSERFEES@fda.hhs.gov

By Fax:
301-595-1429 or 301-595-1430

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

FDA'S USER FEE PROCESS

After you have submitted the required information, FDA will begin its User Fee process:

1. Calculate yearly class allocation
2. Calculate quarterly assessment owed by each domestic manufacturer or importer
3. Notification of assessments
4. Collect payment of assessment
5. Resolution of any disputes, if necessary

STEP 1: CALCULATE YEARLY CLASS ALLOCATION

Every fiscal year, FDA will allocate the total assessment among cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco.

To determine the Yearly Class allocation, FDA will:

1. For each class, multiply the units of product removed and not tax exempt for the most recent calendar year (per published TTB records) by the 2003 maximum Federal excise tax rate for that class to determine the class dollar amount (cigar class percentage share will be the sum of this calculation for the small and large cigar subclasses).
2. Add the calculated dollar amounts found in (1) for all six classes of tobacco products.
3. Divide amount found in (1) by amount found in (2).
4. Multiply amount found in (3) by amount specified in section 919(b)(1) of the FD&C Act.

STEP 2: CALCULATE QUARTERLY ASSESSMENT

The assessment for each class of tobacco product is allocated among the domestic manufacturers and importers in that class, so that each assessment is proportional to its percentage share within a given class. To calculate individual quarterly assessments within each tobacco product class, FDA will:

5. Within each tobacco class, divide the Federal excise taxes reported for each domestic manufacturer or importer by the total reported for all domestic manufacturers and importers. If the percentage share is less than .0001 percent, an individual assessment is not issued.
   a) For the **cigarette, snuff, chewing tobacco, roll-your-own tobacco**, and **pipe tobacco** classes, FDA will calculate the percentage share based on the totals for the prior fiscal *quarter*.
   b) For the **cigar** class, FDA will calculate the percentage share based on the total reported excise taxes for the prior fiscal *year*.
6. Divide yearly class allocation for the given tobacco class by four (known as the quarterly class allocation).
7. Multiply amount found in (5) by amount found in (6).

STEP 3: NOTIFICATION OF ASSESSMENTS

FDA will notify you of your quarterly assessment **no later than 30 calendar days** before the end of each fiscal quarter.

Notification will include:

- Amount of the quarterly assessment
- Date that payment is due
- Each class' initial percentage share
- Each class' quarterly assessment
- Any reallocation amount, and corresponding class percentage share
- Your percentage share for each class and invoice amount
- Any applicable adjustments (see 21 CFR 1150.9(b))
- Directions on how to remit assessments to FDA
- Information regarding interest for late payments
- Information regarding where and when to send disputes

STEP 4: PAYMENT

- FDA must receive your payment no later than the due date listed on the invoice.
- U.S. Dollars only
- Payment must be made in the manner specified in the notification
- Interest will begin accruing once an assessment is not received on time. After 90 days, the assessment will be submitted to a debt collection agency for collections. At this point, firms can enter a payment agreement if they are unable to pay the assessment in full.

STEP 5: DISPUTES

You may dispute an FDA assessment. Note that an assessment must still be paid, even if a dispute is submitted.

A dispute must:

- Include the basis for your dispute.
- Be legible, in English, and submitted in writing.
- Be received by FDA no later than **45 days** after the date on the assessment notification.
- Be emailed to TobaccoUserFees@fda.hhs.gov or mailed to:

  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

STEP 5: DISPUTES CONT.

FDA will review a dispute to determine the validity of the assessment and the accuracy of the market share calculation.

- If FDA determines that the assessment was too high, FDA will apply a credit for the amount assessed in error to the following quarterly invoice or issue a refund by request.
- FDA will respond to the dispute and provide directions on how to submit a request for further Agency review.
  - Request for further Agency review must also be legible, in English, and in writing.
  - FDA must receive the request within 30 days from the date on FDA's response to the original dispute.

PENALTIES

Failure to Pay Assessed User Fees

- 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))

Failure to Report Required Information

- 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))

Submitting False Information

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

NON-COMPLIANCE

For firms with pending Substantial Equivalence Reports:

FDA is unable to issue an order finding a new tobacco product described in a pending or future substantial equivalence (SE) Report -- other than for products marketed between February 15, 2007 and March 22, 2011, and for which an SE report was submitted by March 22, 2011— to be substantially equivalent to the predicate tobacco product until a firm has paid its assessed fees in their entirety.

Note: Entering a repayment plan for assessed user fees does ***not*** render a product compliant with the requirements of the FD&C Act.

HELPFUL INFORMATION

- Resources for You – Small Business Assistance

  https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm20082665.htm

- Guidance

  https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM499356.pdf