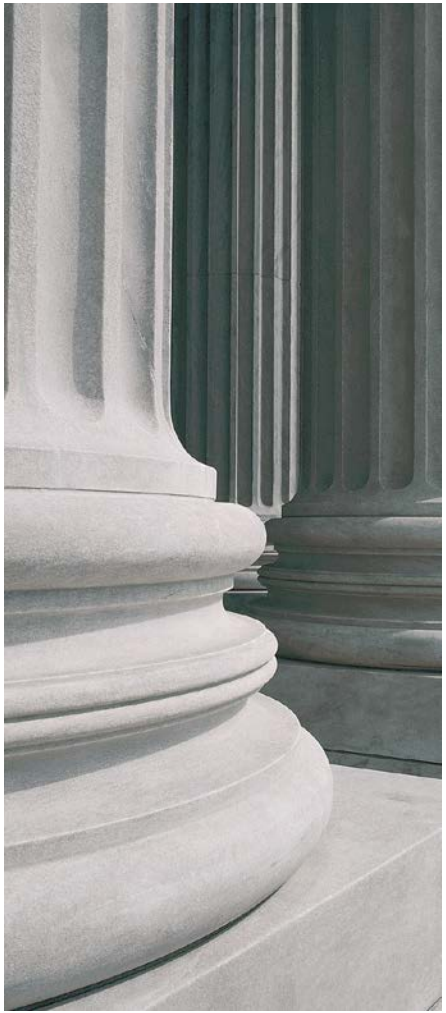
21 CFR PART 1150 USER FEES – SUBMISSION OF DATA NEEDED TO CALCULATE USER FEES FOR DOMESTIC MANUFACTURERS AND IMPORTERS OF TOBACCO PRODUCTS



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Center for Tobacco Products

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HISTORY OF THE RULE

Rulemaking Activities

- The Notice of Proposed Rulemaking (NPRM) was issued on May 31, 2013

- 75 day public comment period

- The Final Rule was issued on July 10, 2014 and became effective on August 11, 2014

DOES THIS RULE APPLY TO ME?

***What*:** 21 CFR Part 1150

***Who*:** Domestic Manufacturers and Importers of these tobacco products:

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

***Note*:** Currently, user fees are only assessed on and collected from the four classes of currently regulated tobacco products (cigarettes, snuff, chewing tobacco, and roll-your-own tobacco).

IMPORTANT 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.

WHEN DO I SUBMIT THE INFORMATION?

FDA must receive the required information by the **20th** of each month

- **Began October 2014**
- **Every Month**, you are required to submit
- Submission must be received by FDA **no later than the 20th day of each month**

WHAT INFORMATION DO I 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 name and the mailing address of the principal place of business of the domestic manufacturer or importer
- A contact name and phone number
- BOTH an email address AND postal address where 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 permit.***
- ***Must be reported even if zero tobacco products were removed.***

"units of product"

Cigarettes: number of sticks

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

"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.

"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 previously discussed Removal Information

  AND

  - The payment of the Federal excise taxes.

HOW DO I SUBMIT THIS INFORMATION?

Form FDA 3852

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

WHERE DO I SEND THIS INFORMATION?

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

By Fax:

301-595-1429 or 301-595-1430

WHAT IS FDA'S USER FEE PROCESS?

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

Process will include:

Step 1: Calculate yearly class allocation.

Step 2: Calculate quarterly assessment owed by each domestic manufacturer or importer.

Step 3: Notification of assessment.

Step 4: Resolve any disputes. (If Necessary)

Step 5: Collect payment of assessment.

Step 6: Enforce penalties. (If Necessary)

STEP 1: CALCULATE YEARLY CLASS ALLOCATION

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

Yearly Class allocation determined by:

1. multiplying the units of product removed and not tax exempt for the most recent calendar year by the 2003 maximum Federal excise tax rate for that class or subclass to find the class dollar amount.
2. Then, adding the total dollar amounts for these classes of products for the most recent calendar year.
3. Then, dividing amount found in (1) by amount found in (2).
4. Then, multiply amount found in (3) by amount specified in section 919(b)(1) of the FD&C Act.

STEP 2: CALCULATE QUARTERLY ASSESSMENT

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

Quarterly assessment for each domestic manufacturer/importer determined by:

5. Divide the Federal excise taxes it paid (by class) for prior quarter by the total paid by all domestic manufacturer/importers (by class) for that same quarter. (If the amount found in (1) is less than 0.0001 percent, share excluded from assessment.)
6. Divide yearly class allocation found in (4) by four.
7. Multiply amount found in (6) by amount found in (5).
8. Finally, truncate amount found in (7) to the fourth decimal place.

(There will be a separate assessment for each class of tobacco product.)

STEP 3: NOTIFICATION

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
- Directions on where and when to send disputes

STEP 4: DISPUTES

You may dispute an FDA assessment.

Your 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 sent 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 4: DISPUTES

- After reviewing your dispute, if FDA determines that your assessment was too high, FDA will refund the amount assessed in error.
- After receiving your dispute, FDA will send you its response which will provide directions on how you can submit a request for further Agency review.
- This request submission must be legible, in English, and in writing.
- FDA must receive the request within 30 days from the date on FDA's response.

STEP 5: PAYMENT

- FDA must receive your payment **no later than the last day** of each fiscal quarter.
- U.S. Dollars only
- Payment must be in made in manner specified in the notification.
- Interest will begin accruing once an assessment is not received on time.
- If FDA does not send timely notification, interest will not begin accruing until after 30 calendar days have elapsed from the date FDA does send notification.
- NOTE – Even if you dispute an assessment amount, you must still pay the assessment on time and as directed in your notification.

STEP 6: PENALTIES

Failure to Pay Assessed User Fees

- Adulterated under section 902(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Failure to Report Required Information

- Adulterated under section 902(4) FD&C Act
- Prohibited Act under 301(e) FD&C Act

Submitting False Information

- Title 18 U.S.C.

HELPFUL INFORMATION

- Resources for You – Small Business Assistance
  - http://www.fda.gov/tobaccoproducts/resourcesforyou/ucm189635.htm
- Final Rule
  - http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM404355.pdf
- Guidance
  - http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/ForManufacturers/UCM405202.pdf