United States Food and Drug Administration

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

OMB Control No. 0910-0749

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration regulations. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) (sections 900 through 920) (21 U.S.C. 387-387t). Specifically, Section 919 of the Act (21 U.S.C. 387s) governs tobacco user fees.

Section 919(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. Accordingly, Section 919(b)(2)(B)(i) identifies those tobacco products as: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

Section 919(b)(1) specifies the total amount of user fees to be collected for each fiscal year and under section 919(a) FDA is 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 first among the classes of tobacco products (yearly class allocation) and then among the domestic manufacturers and importers within each tobacco class (individual market share). The yearly class allocation is based on volume of tobacco product removed[1] into commerce for each tobacco class. The individual market share is based on entities share of the market for that tobacco product class and calculated using Federal excise tax data.

To implement the tobacco user fee program as prescribed in the FD&C Act (as summarized above), FDA must collect the information needed to accurately calculate tobacco user fee assessments. FDA published a final rule, 21 CFR Part 1150, that requires domestic manufacturers and importers of the applicable tobacco products (listed above) to submit this information to the FDA.

The following sections of the final rule include collections of information. The information captured by these sections is necessary to provide FDA with the information necessary to accurately assess and collect tobacco user fees from each domestic manufacturer and importer of tobacco products subject to tobacco user fees.

[1] 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."

Section 1150.5 covers essential information enabling FDA to determine allocations and verify monthly summary information on which the allocations are based on. FDA can accurately assess and collect user fees from domestic manufacturers and importers of tobacco products subject to tobacco user fees. Submission of the information in a summary form (FDA 3852) along with the supporting documents (i.e., certified copies of the relevant tax forms) ensures that FDA can efficiently and accurately identify the amount of tobacco product removed by class and the amount of Federal excise taxes assessed for those removals. FDA believes that the required information provides the Agency the data necessary to effectively implement its legislative requirements in Section 919 of the FD&C Act.

Paragraph 1150.5(a) describes when and in what manner FDA requires domestic manufacturers and importers of tobacco products subject to tobacco user fees to submit information. Paragraph 1150.5(b)(1) and (b)(2) describe the information that FDA requires domestic manufacturers and importers of tobacco products subject to tobacco user fees to provide monthly. Moreover, FDA provides form FDA 3852 to domestic manufacturers and importers. FDA requires the use of this form to capture the monthly identification and removal information specified under § 1150.5(b)(1) and (b)(2).

Specifically, under § 1150.5(b)(1), each domestic manufacturer and importer submits identifying information, including its name and address, contact name and telephone number, an email address and postal address for FDA notifications, Alcohol and Tobacco Tax and Trade Bureau (TTB) permit number, and Employer Identification Number (EIN).

Under § 1150.5(b)(2), each domestic manufacturer and importer submits removal information to include the units of products, by class, removed and not tax exempt for the prior month and the Federal excise taxes assessed, by class, for those removals. This sub-paragraph requires monthly reports from all domestic manufacturers and importers even if entities had no removals subject to tax during the reporting period.

Lastly, § 1150.5(b)(3) requires that domestic manufacturers and importers of tobacco products subject to tobacco user fees provide monthly certified copies of returns and forms related to the removal of tobacco products into domestic commerce (Section 5702 of the IRC) and the payment of Federal excise taxes imposed (Chapter 52 of the IRC). Because the specific names of non-FDA reports and forms may change over time, FDA does not name reports or forms in the final rule; FDA specifies the form names on Form FDA 3852. Currently, the forms include: TTB Form 5220.6; TTB Form 5210.5; TTB 5000.24; and CBP Form 7501. The burden on reporting entities should be relatively low because are submitting copies of forms they are currently required to submit under separate laws. Note that the cost and hourly burden listed in Table 1 for § 1150.5(b) covers the burden for all paragraphs in § 1150.5.

Section 1150.13 covers necessary information to collect assessments identifying which domestic manufacturers and importers have paid their assessments, and to calculate interest on unpaid manufacturer and importer assessments. This section requires that a domestic manufacturer and importer pay an assessment by the last day of the applicable quarter. If FDA has 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 final rule provides that no interest is assessed until 30 calendar days after the date FDA sent notification of the amount owed. This section also requires that payments be submitted in U.S. dollars and in the manner specified in the notification (for example, online payment).

Section 1150.15 covers information necessary to notify FDA of domestic manufacturer or importer disputes. FDA will provide a dated, written response and FDA's response will provide information about how to submit a request for further Agency review. Specifically, § 1150.15(a) requires that domestic manufacturers and importers submit any dispute in writing, within 45 days of the date of the assessment notification, that the dispute be legible and in English, and that the dispute be sent to the address identified on FDA's tobacco products website. If FDA determines that there is an error in the amount of the assessment, FDA will credit the necessary amount to the next quarterly invoice or refund the amount. To ensure finality in FDA's accounts and potential refund obligations, FDA believes it is necessary to have a time limit on disputes over user fee assessments. FDA believes the timeframe identified is adequate to detect an issue and prepare a written dispute. Further, § 1150.15(d) provides that any request for further Agency review under 21 CFR 10.75 be submitted in writing within 30 days of the date of FDA's response to the dispute (submitted under § 1150.15(a)). FDA believes this timeframe is adequate to detect a continued issue and to prepare a written request for further review. Along with the timeframe in § 1150.15(a), this timeframe ensures finality in FDA's accounts and potential refund obligations.

On August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA's rule deeming tobacco products to be subject to FDA's tobacco product authorities "insofar as it applies to premium cigars". FDA is working to develop a reporting mechanism that will allow for FDA to identify non-premium cigars.

Accordingly, we request extension of OMB approval for the information collection provisions and the associated agency form, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to require each domestic manufacturer or importer of tobacco products subject to tobacco user fees to submit to FDA information necessary to calculate and assess user fees under section 919 of the FD&C Act. FDA will collect this information to ensure that it has the information necessary to calculate, assess, and collect tobacco user fees. In addition, the collection of information allows the domestic manufacturer or importer the ability to request further review of their assessment if there is a dispute over the amount of the user fee assessed by FDA.

3. Use of Improved Information Technology and Burden Reduction

To make reporting requirements for this collection easier for respondents, FDA created Form FDA 3852 to provide user fee submission information electronically. Domestic manufacturers and importers must complete and submit this form to FDA via e-mail, fax, or mail. Based on its experience with submittals, FDA estimates approximately 80-90 percent of all respondents will submit the information in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

As referenced in the previous terms of clearance, the data collected under this ICR overlaps with collections of excise tax and import information by Alcohol and Tobacco Tax and Trade Bureau (TTB) and Customs and Border Protection (CBP). However, TTB and CBP data cannot currently be used by FDA for calculating quarterly tobacco user fee assessments due to both logistical reasons and restrictions on the use of excise tax information provided to FDA directly by TTB. In meeting with TTB, FDA identified legal restrictions that are outlined in the Internal Revenue Code law(s), specifically section 6103, that does not allow for the direct utilization of excise tax data (and other associated data) received directly from TTB and CBP to fully implement FDA's Tobacco User Fee Program—especially in calculating quarterly tobacco user fee assessments. FDA continues to communicate with the TTB and CBP to obtain certain information from each organization that allows the FDA to verify and validate our records received from industry to ensure accurate tobacco user fee assessments.

5. Impact on Small Businesses or Other Small Entities

All domestic manufacturers and importers of tobacco products subject to regulation under chapter IX of the FD&C Act are affected by this rule, including small businesses. It is likely that about 85 percent of the affected entities (approximately 220 entities) would be considered small tobacco product manufacturers under the definition included in section 900 of the FD&C Act.[2] The actual user fees paid by small entities are likely smaller than those paid by larger businesses because user fees are assessed based on the percentage share by class of tobacco products and by individual company within each tobacco product class.

FDA continues to pursue means of reducing the reporting burden for both small and large respondents to this collection of information and continues to employ the latest technology for receiving user fee information, consistent with the intent of the legislation.

FDA aids small businesses in dealing with the information submission requirements of this collection of information by providing technical, nonfinancial assistance in submitting the information required for user fees.

6. Consequences of Collecting the Information Less Frequently

The collection of information submitted is used to meet the requirements of section 919 of the FD&C Act regarding user fees. Because the information collection is derived from information collected monthly by other agencies (i.e., TTB and CBP), we believe that collecting this information less frequently will not allow FDA to meet its statutory obligations for assessing and collecting equitable user fees from domestic manufacturers and importers of tobacco products.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection has one special circumstance associated that would be inconsistent with the regulation. Specifically, FDA expects respondents to provide monthly reporting as required in § 1150.5. Additionally, respondents may provide voluntary premium cigar data monthly as herein.

[2] This is based on counts of tobacco product manufacturer and importer EINs from 2023 TTB data and Census Bureau 2021 Statistics of U.S. Business data (https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html) on establishments with 500 or fewer employees (the closest reported threshold to the small tobacco product manufacturer 350 employee threshold).

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of May 1, 2025 (90 FR 18687), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift awarded to respondents of this collection of information.

10. Assurance of Privacy Provided to Respondents

All data will be collected with an assurance that the respondents' answers remain private to the extent allowed by law and consistent with the FDA Privacy Act System of Records #09-10-0021 (FDA User Fee System). Private information is protected from disclosure under the Freedom of Information Act (FOIA) under section 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the Agency's regulations (21 CFR part 20).

Privacy is assured by enacting procedures to prevent unauthorized access to respondent data and by preventing the public disclosure of the responses of individual participants.

All electronic data is maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35.

CTP consulted with FDA's Privacy office, which conducted a Privacy Impact Assessment (PIA). CTP received HHS approval on the privacy impact assessment and was assigned PIA ID FDA2107988.

11. Justification for Sensitive Questions

FDA is not asking questions of a sensitive nature in this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1. Estimated Annual Reporting Burden[1]

21 CFR Section/Activity	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Hours per Response	Total Hours
1150.5(a), (b)(1) and (2), and Form FDA 3852; Identification and removal information (monthly)	820	12	9,840	3	29,520
Voluntary premium cigar data submission (monthly)	50	12	600	1.5	900
1150.5(b)(3); Certified copies (monthly)	820	12	9,840	1	9,840

Table 1. Estimated Annual Reporting Burden[1]

21 CFR Section/Activity	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Hours per Response	Total Hours
1150.13; Payment of user fee assessment (quarterly)	319	4	1,276	1	1,276
1150.15(a); Submission of user fee dispute (annually)	2	1	2	10	20
1150.15(d); Submission of request for further review of dispute of user fee (annually)	1	1	1	5	5
Total			21,559		41,561

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

FDA estimates that entities will submit tobacco product user fee reports for approximately 820 TTB permits in a given month. FDA considered the number of active TTB permits (based on TTB data) in FY23 for domestic manufacturer and importers of tobacco products subject to tobacco user fees to estimate the responses for §1150.5. FDA estimates it will take 3 hours for each of these submission types for a total of 29,520 hours annually. This is an increase of 120 respondents and 4,320 hours annually. Under § 1150.5(b)(3), these respondents are also expected to provide monthly 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 to FDA. We estimate that each monthly report will take 1 hour for a total of 9,840 hours annually, which is an increase of 1,440 hours.

FDA expects 50 respondents to submit voluntary premium cigar data monthly, which takes an average of 1.5 hours per response, 12 times per year, totaling 900 hours. This reflects a reduction in 50 respondents from 100 to 50 and a reduction in average burden per response from 2.5 hours to 1.5 hours. FDA updated this data based on reasonable estimates of the burden of voluntary submissions in FY24. There may be some fluctuations in this number.

The estimate of 319 respondents submitting payment of user fee information under §1150.13 reflects a decrease of 57 respondents. FDA considered the number of user fee assessments issued to domestic manufacturers and importers of tobacco products subject to tobacco user fees on average each quarter for FY23. Note, entities may have more than one TTB permit, however, tobacco user fee assessments are aggregated based on EIN and not TTB permit number. Therefore, we expect the number of respondents to be lower for § 1150.13.

FDA estimates that two of the respondents assessed user fees will dispute the amounts under § 1150.15(a), for a total of 20 hours. FDA also estimates that one respondent who disputes their user fees will ask for further review by FDA under §1150.15(d), for a total amount of 5 hours. FDA considered the historical submission of tobacco user fee disputes and requests for additional Agency review.

As previously stated, FDA is working to develop a reporting mechanism that will allow for FDA to identify non-premium cigars which may include an update to Form FDA 3852. In the meantime, domestic manufacturers and importers of cigars may voluntarily report data for "premium cigars".

As part of the current monthly report, the regulations require submitting "[t]he 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." FDA uses this and other information to calculate tobacco product user fee assessments. Beginning with August 2023 removals (reports that were due September 20, 2023), FDA would explain that a domestic manufacturer or importer of cigars, in addition to the currently required information—may also submit the three data elements below for products that are "premium cigars" as defined in the court order:

- The number of units removed and not tax exempt (block 10A for manufacturers and 10C for importers)
- The Federal excise tax paid for those removals (block 10B for manufacturers and 10D for importers)
- The supporting documentation identifying the removals and associated Federal excise taxes (attached to FDA 3852)

FDA suggests domestic manufacturers and importers of cigars use the existing FDA 3852 form, page 2, row 10 to report any additional information; they may enter both the non-premium and premium cigar volume and taxes in cells 10A through 10D as appropriate. Responders may use the current methods of submission for the monthly reports:

- Email: TobaccoUserFees@fda.hhs.gov (preferred method)
- Fax: 301-595-1429 or 301-595-1430
- 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

12b. Annualized Cost Burden Estimate

Table 2. Estimated Annual Cost Burden[1]

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco product manufacturers and importers	41,561	$153.96	$6,398,731.56

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

FDA assumes that a submission will likely involve the work of tobacco manufacturing management occupations and legal occupations. Referencing 2023 Bureau of Labor Statistics national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry, FDA has estimated that the wage is $153.96 per hour. This wage represents a mix of 50 percent management (11-0000, $73.88/hour) and 50 percent legal occupations (23-0000, $80.08/hour) and is doubled to account for benefits and overhead. FDA estimates the reporting cost to respondents is $6,398,731.56. This figure was derived by multiplying the total reporting burden hours from Table 1 (41,561) by an hourly rate of $153.96.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no capital, operating, or maintenance cost associated with this information collection.

14. Annualized Cost to Federal Government

Our estimated cost to the Federal government reflects the allocation of 2 full-time equivalent employees who collect, process, and file responses related to the payment, submission, or dispute of user fees. Using 2025 Grade 13 Step 4 salary and wage data for the Washington DC-Metropolitan area found at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/html/DCB.aspx and doubling to account for benefits and overhead, we calculate a total cost of $530,552 ($132,638 x 2 x 2).

15. Explanation for Program Changes or Adjustments

FDA estimates the total annual burden for this collection of information is 41,561 hours. The estimated burden for the information collection reflects an overall increase of 3,377 hours. We attribute this adjustment to an increase in the number of entities submitting tobacco user fee information to FDA.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency has no plans for the tabulation and publication of this collection of information.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with this collection of information.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.