4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2193]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0749. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 Number 0910-0749-Extension

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) (sections 900 through 920) (21 U.S.C. 387-387t). Specifically, section 919 of the FD & C 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) of the FD&C Act (21 U.S.C. 387s (b)(2)(B)(i)) identifies those tobacco products as: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

FDA utilizes Form FDA 3852, entitled "Report of Tobacco Product Removals Subject to Tax for Tobacco Product User Fee Assessment", to facilitate the collection of data necessary for calculating tobacco product user fee assessments. This form is used by domestic manufacturers and importers of tobacco products to report the quantity of products removed from manufacturing facilities or imported into the United States for sale.

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. On May 10, 2016, FDA published a final rule that requires domestic manufacturers and importers of the applicable tobacco products (listed above) to submit this information to the FDA (81 FR 28707).

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.

FDA estimates the burden of this collection of information as follows:

Table 1. --Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Average Burden per Response in Hours	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
1150.5(b)(3); Certified copies (monthly)	820	12	9,840	1	9,840
Voluntary premium cigar data submission (monthly)	50	12	600	1.5	900
1150.13; Payment of user fee assessment (quarterly)	319	4	1,276	1	1,276
1150.15(a); Submission of user fee dispute (at discretion of respondent)	2	1	2	10	20
1150.15(d); Submission of request for further review of dispute of user fee (at discretion of respondent)	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.

We have revised our burden estimates to this information collection request. 21 CFR 1150.5 is reflecting an increase in 120 respondents from 700 to 820. FDA requires the use of Form FDA 3852 to capture the monthly identification and removal information specified under § 1150.5(b)(1) and (b)(2). The form also directs manufacturers and importers to attach supporting documentation required by § 1150.5(b)(3). FDA considered the number of active Alcohol and Tobacco Tax and Trade Bureau (TTB) permits (based on TTB data) in FY23 for domestic manufacturers and importers of tobacco products subject to tobacco user fees.

Voluntary premium cigar data submission (monthly) is reflecting a reduction in 50 respondents from 100 to 50 and a reduction in average burden per response from 2.5 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.

Section 1150.13 (21 CFR 1150.13) is reflecting a reduction in 57 respondents from 376 to 319. 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 Employer Identification Number and not TTB permit number. Therefore, we expect the number of respondents to be lower for § 1150.13.

21 CFR 1150.15(a) is reflecting a reduction in 3 respondents from 5 to 2, and 21 CFR 1150.15(d) is reflecting a reduction in 2 respondents from 3 to 1 and a reduction in average burden per response from 10 to 5 hours. FDA considered the historical submission of tobacco user fee disputes and requests for additional Agency review.

The cumulative changes to the estimated burden for this information collection reflects an overall increase of 3,377 burden hours and a corresponding increase of 2,047 responses.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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