Unlike manufacturers, device user facilities are not required to submit malfunction reports under part 803. User facilities, such as hospitals or nursing homes, are required to submit MDRs to FDA and/or the manufacturer only for reportable death or serious injury events. (See section 519(b) of the FD&C Act; 21 CFR 803.30(a).) We believe that by permitting alternative reporting for certain devices, the VMSR Program may reduce burden on respondents who elect to participate and are otherwise subject to mandatory requirements.

Special controls established in the final order ''Microbiology Devices; Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests'' to support the class II classification of certain HIV serological diagnostic and supplemental tests (21 CFR 866.3956) and for HIV NATs diagnostic and supplemental tests (21 CFR 866.3957) require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional premarket notification (510(k)) submission for these devices. (Information collections associated with premarket notification (510(k)) are approved under OMB control number 0910–0120.) Although manufacturers of HIV serological diagnostic and supplemental tests and HIV NAT diagnostic and supplemental tests are already required to maintain complaint files and to review and evaluate complaints for these devices under 21 CFR 820.198, special controls are necessary to provide a reasonable assurance of safety and effectiveness of these devices. (Information collections associated with Quality System requirements under 21 CFR part 820 are approved under OMB control number 0910–0073.) We estimate it will take a manufacturer approximately 3 hours annually to review their existing records, prepare the complaint log, and submit to FDA.

We assume a cost of $10 associated with the payment of an annual fee to maintain e-certification will apply to each respondent. We estimate a total operating and maintenance cost of $18,710 ($10 × 1,871 respondents).

Since the last OMB approval, we have adjusted the respondent and response estimates based on FY 2024 data. We also adjusted the Average Burden per Response for ''Exemptions—803.19'' and ''Importer Reporting, Death and Serious Injury—803.40 and 803.42'' from 0.1 hour to 1 hour to correct an error introduced in a previous request for extension of this information collection. These adjustments have resulted in an overall increase of 1,527,443 total responses, and a corresponding increase of 323,806 total burden hours.

We are revising this information collection to add the FDA guidance entitled ''Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers'' (August 2024; *https://www.fda.gov/media/163692/download*), which is intended to help manufacturers better understand and use the VMSR Program. The guidance does not affect the burden estimates.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14230 Filed 7–28–25; 8:45 am]

BILLING CODE 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 August 28, 2025.

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	Number of respondents	Number of responses per respondent	Total number 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.

[FR Doc. 2025–14221 Filed 7–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Deafness and Other Communication Disorders Advisory Council, September 04, 2025, 01:00 p.m. to September 05, 2025, 01:05 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on July 21, 2025, 90 FR 34281.

The meeting time has been changed from 9:00 a.m. to 9:40 a.m. to 9:30 a.m. to 10:00 a.m. The meeting is partially Closed to the public.

Dated: July 24, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–14239 Filed 7–28–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the National Institute On Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.

Date: May 19–21, 2026.

Time: May 19, 2026, 8:00 a.m. to 4:30 p.m.

Agenda: Executive Session; Board Business; Review of Labs and PI's; Adjournment.

Address: National Institute of Aging, 251 Bayview Blvd., Baltimore, MD 21224 (Virtual Meeting).

Time: May 20, 2026, 8:00 a.m. to 4:30 p.m.