TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity; 21 CFR section	Number of record-keepers [2]	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Rodent and Other Pest Control; § 118.10(a)(3)(ii), and Biosecurity Records; § 118.10(a)(3)(i).	9,462	52	492,024	0.5 (30 minutes)	246,012
Prevention Plan Design; § 118.10(a)(1)	350	1	350	20	7,000
Cleaning and Disinfection Records; § 118.10(a)(3)(iii).	331	1	331	0.5 (30 minutes)	166
Total					393,857

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Some records are kept on a by-farm basis and others are kept on a by-house basis.
[3] Calculations include requirements for pullet and layer houses.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Registrations or Updates; § 118.11	FDA 3733 [2]	350	1	350	2.3	805
Cancellations; § 118.11	FDA 3733	30	1	30	1	30
Total						835

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *http://www.access.fda.gov* per § 118.11(b)(1).

Our estimates for the recordkeeping burden and the reporting burden are based on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18617 Filed 9–24–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0350]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

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 October 27, 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 0910–0732. 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.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0732—Extension

This information collection supports FDA regulations. Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). The FD&C Act provides FDA with the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. FDA has the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b)). In accordance with that authority, FDA issued a rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority (81 FR 28974, May 10, 2016). The definition of the term ''tobacco product'' in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) products that contain nicotine from any source. As a result, non-

tobacco nicotine (NTN) products (*e.g.,* products containing synthetic nicotine) are subject to all of the tobacco product provisions in the FD&C Act. Although NTN products are now subject to all of the tobacco product provisions in the FD&C Act, including section 904 provisions of the FD&C Act, FDA does not expect cigarettes, RYO tobacco, and smokeless tobacco products, for which Form FDA 3787a-j was developed, to also include NTN products.

Chapter IX of the FD&C Act applies to regulated tobacco products, including sections 904(a)(3) and (c)(1) (21 U.S.C. 387d(a)(3) and (c)(1)). Section 904(a)(3) of the FD&C Act requires the submission of an initial report from each tobacco product manufacturer or importer, or agents thereof, listing all constituents, including smoke constituents as applicable, identified as a harmful and potentially harmful constituent (HPHC) to health by FDA. Reports must be by brand and by quantity in each brand and subbrand.

Section 904(c)(1) of the FD&C Act provides that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide the information reportable under section 904(a)(3) of the FD&C Act at least 90 days prior to introducing the product into interstate commerce.[1]

FDA has taken several steps to identify HPHCs to be reported under section 904 of the FD&C Act, including issuing a guidance discussing FDA's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' in the context of implementing the HPHC list requirement under section 904(e) of the FD&C Act (76 FR 5387, January 31, 2011, revised guidance issued August 2016). The guidance is available on the internet at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/harmful-and-potentially-harmful-constituents-tobacco-products-used-section-904e-federal-food-drug.* The current established list of HPHCs also is available on the internet at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list* (77 FR 20034, April 3, 2012).

The purpose of the information collection is to collect statutorily mandated information regarding HPHCs in certain tobacco products and tobacco smoke, by brand and by quantity in each brand and subbrand.

To facilitate the submission of HPHC information, Forms FDA 3787a-j, for cigarettes, smokeless tobacco products, and RYO tobacco products, respectively, in both paper and electronic formats, are available. Additionally, FDA is developing forms to facilitate the submission of HPHC information for the deemed tobacco products. We intend to model these forms on the current HPHC reporting forms (*i.e.,* Forms FDA 3787a-j).

Manufacturers or importers, or their agents, will be able to submit HPHC information either electronically through new web forms within the Center for Tobacco Products (CTP) Portal Next Generation or in paper format. The modernized web forms will streamline data entry and submission for reporting HPHCs for cigarettes, smokeless tobacco products, and RYO tobacco products. This process will be more efficient than the current approach, which requires the use of the FDA's eSubmitter Desktop Tool for data entry and the CTP Portal web application for submission. With CTP Portal Next Generation, necessary tasks will be completed directly within the web forms, making HPHC submissions more user-friendly.

In the **Federal Register** of June 27, 2025 (90 FR 27617), 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]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting for Section 904(c)(1) Products					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	243	1	243	1.82	442
RYO	10	1	10	0.43	4
Smokeless	32	1	32	0.63	20
Total					466
2. Testing of HPHC Quantities in Products					
Cigarette Filler and RYO	10	1	10	9.42	94
Smokeless	32	1	32	12.06	386
Total					480
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: ISO Regimen	243	1	243	23.64	5,745
Cigarette: Health Canada Regimen	243	1	243	23.64	5,745
Total					11,490
Total Section 904(c)(1) Reporting Burden Hours					12,436

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

[1] Note that section 904(c)(1) testing and reporting requirements are separate from the requirements that must be satisfied before a new tobacco product (sections 905 and 910 of the FD&C Act (21 U.S.C. 387e and 387j)), or modified risk tobacco product (section 911 of the FD&C Act (21 U.S.C. 387k)) may be marketed.

We have revised our burden estimates to this information collection request. Our burden estimates have been updated based on the assumption that ''Each respondent represents a statutory tobacco product that receives authorization from FDA for which manufacturers and importers (or their agents), must report their product information to FDA under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce for all new products.'' Under this assumption, the number of respondents is equal to the number of total annual responses FDA estimated from previous submissions. This assumption will facilitate future burden estimates, allow us to refine the estimated burden to include only the products that need to report HPHCs under section 904(c)(1) of the FD&C Act, and avoid data suppression issues with disaggregated Alcohol and Tobacco Tax and Trade Bureau data.

- Cigarette—section 904(c)(1) Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms/Testing of HPHC is reflecting a reduction in 137 respondents from 380 to 243.
- Roll Your Own Tobacco Product—section 904(c)(1) Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms is reflecting a reduction in 9 respondents from 19 to 10.
- Smokeless—section 904(c)(1) Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms is reflecting an increase in 7 respondents from 25 to 32.

The cumulative changes to the estimated burden for this information collection reflects an overall decrease of 6,727 burden hours and a corresponding decrease of 139 responses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18613 Filed 9–24–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0354]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed

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 October 27, 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 0910–0339. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Substances Prohibited From Use in Animal Food or Feed

OMB Control Number 0910–0339—Revision

This information collection supports implementation of statutory and regulatory requirements. Epidemiological evidence gathered in the United Kingdom has suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. Agency regulation at § 589.2000 (21 CFR 589.2000), authorized by section 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(a)), provides that animal protein derived from mammalian tissue (with some exclusions) is not generally recognized as safe (GRAS) for use in ruminant feed and is a food additive subject to certain provisions of the FD&C Act (62 FR 30936, June 5, 1997). The regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain, or may contain, protein derived from mammalian tissue, and feeds made from such products.

Specifically, § 589.2000(e)(1)(iv) requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution to maintain written procedures specifying the cleanout procedures or other means and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize consistent processes, and then to help inspection personnel confirm that the firm is conducting these processes in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being followed when they are conducting an inspection. These written procedures must be maintained if the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process, the record must be updated. Consistent with § 589.2000(h), written procedures shall be made available for inspection and copying by FDA, and records made available for inspection and copying by FDA must be retained for 1 year.

Description of Respondents: Respondents include renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution.

In the **Federal Register** of September 2, 2025, 90 FR 27630, we published a 60-day notice soliciting public comment on the proposed collection of information. Two comments were received but did not respond to the information collection topics solicited under 5 CFR 1320.8(d)(2). We also note an inadvertent calculation error which we have corrected.