this applicant seeks 650 or 860 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18781 Filed 9–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0352]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States

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 29, 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 0910–0775. 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, 10 a.m.–12 p.m, 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.

Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

OMB Control Number 0910–0775—Extension

This information collection supports Food and Drug Administration guidance. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Tobacco products are governed by chapter IX of the FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 387t). Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended, defines a tobacco product as any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Section 910 of the FD&C Act sets out premarket requirements for new tobacco products. The term new tobacco product is defined as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (section 910(a)(1) of the FD&C Act).

FDA refers to tobacco products that were commercially marketed (including those products in test markets) in the United States as of February 15, 2007, as Pre-Existing tobacco products. Pre-Existing tobacco products are not considered new tobacco products and are not subject to the premarket requirements of section 910 of the FD&C Act. The guidance document associated with this information collection provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. A Pre-Existing tobacco product (except such products exclusively in test markets) may also serve as the predicate tobacco product in a section 905(j) report (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)A)(i)) of the FD&C Act.

The guidance document ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (Revised)'' (2023) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007-revised*) recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

In the **Federal Register** of June 27, 2025 (90 FR 27632), 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 (in hours)	Total hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	500	1	500	5	2,500

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

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the Pre-Existing status of a tobacco product under the guidance is not required and also on the number of Pre-Existing tobacco product submissions received from 2011 to October 2024. All new tobacco products require a marketing authorization order from FDA before introducing such products in the U.S. market. If a deemed new tobacco product was on the market as of August 8, 2016, a marketing application was required to be submitted by September 9, 2020 as required by the Court, and as set forth in the Center for Tobacco Products compliance policy (see exception for premium cigars).[1] A marketing application must be submitted and receive authorization to market a new tobacco product that was not on the market as of August 8, 2016.[2] The number of hours to gather the evidence is FDA's estimate of how long it might take a manufacturer to review, gather, and submit dated information if making a request for Agency determination.

FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it would take approximately 2,500 hours annually to respond to this collection of information.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Our estimated burden for the information collection reflects an overall decrease of 2,500 hours and a corresponding decrease of 500 responses. The number of submissions FDA received to establish marketing as of February 15, 2007 has decreased and we have therefore revised the number of respondents to the information collection based on this data.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18806 Filed 9–26–25; 8:45 am]

BILLING CODE 4164–01–P

[1] *Cigar Ass'n of Am.* v. *FDA*, No. 16–cv–01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023). FDA has appealed this decision. See *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market.*

[2] See *https://www.fda.gov/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products#:~:text=On%20August%208%2C%202016%2C%20all,authorization%20requirements%20in%20the%20Federal.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0339]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mitigation Strategies To Protect Food Against Intentional Adulteration

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 29, 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 0910–0812. 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.

Mitigation Strategies To Protect Food Against Intentional Adulteration

OMB Control Number 0910–0812—Reinstatement

This information collection supports FDA regulations. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA), certain provisions have been established to protect against the intentional adulteration of food. Section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food and are required to register under section 415 of the FD&C Act (21 U.S.C. 350d). Section 419 of the FD&C Act (21 U.S.C. 350h) addresses intentional adulteration in the context of fruits and vegetables that are raw agricultural commodities. Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk. These provisions are codified at part 121 (21 CFR part 121) and include requirements that an owner, operator, or agent in charge of a facility must:

- Prepare and implement a written food defense plan that includes a vulnerability assessment to identify significant vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions, and verification (§ 121.126 (21 CFR 121.126));
- identify any significant vulnerabilities and actionable process steps by conducting a vulnerability assessment for each type of food manufactured, processed, packed, or held at the facility using appropriate methods to evaluate each point, step, or