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

procedure in a food operation (§ 121.130 (21 CFR 121.130));

• identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated. For each mitigation strategy implemented at each actionable process step, include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step (§ 121.135 (21 CFR 121.135));

• establish and implement mitigation strategies management components, as appropriate to ensure the proper implementation of each such mitigation strategy, taking into account the nature of the mitigation strategy and its role in the facility's food defense system (21 CFR 121.138);

• establish and implement food defense monitoring procedures, for monitoring the mitigation strategies, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (§ 121.140 (21 CFR 121.140));

• establish and implement food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented, as appropriate to the nature of the actionable process step and the nature of the mitigation strategy (§ 121.145 (21 CFR 121.145));

• establish and implement specified food defense verification activities, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (§ 121.150 (21 CFR 121.150));

• conduct a reanalysis of the food defense plan (21 CFR 121.157);

• ensure that all individuals who perform required food defense activities are qualified to perform their assigned duties (§ 121.4 (21 CFR 121.4)); and

• establish and maintain certain records, including the written food defense plan (vulnerability assessment, mitigation strategies and procedures for food defense monitoring, corrective actions, and verification) and documentation related to training of personnel. All records are subject to certain general recordkeeping and record retention requirements (§§ 121.301 through 121.330 (21 CFR 121.301 through 121.330).

Under the regulations, an owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food defense plan, including written identification of actionable process steps, written mitigation strategies, written procedures for defense monitoring, written food defense corrective actions, and written food defense verification procedures.

The purpose of the information collection is to ensure compliance with the provisions under part 121 related to protecting food from intentional adulteration. The regulations are intended to address hazards that may be intentionally introduced to foods, including by acts of terrorism, with the intent to cause widespread harm to public health. Under the regulations, domestic and foreign food facilities that are required to register under the FD&C Act are required to identify and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.

To facilitate the collection of information, FDA offers tools and educational materials related to protecting food from intentional adulteration, including the FDA Food Defense Plan Builder, a user-friendly tool designed to help owners and operators of food facilities develop a personalized food defense plan, and the Mitigation Strategies Database, a database for the food industry providing a range of preventative measures that firms may choose to implement. These and other informational resources are available at *https://www.fda.gov/food/food-defense/food-defense-tools-educational-materials.* FDA also offers a small entity compliance guide titled ''Mitigation Strategies to Protect Food Against Intentional Adulteration'' (August 2017) to inform domestic and foreign food facilities about compliance with regulations to protect against intentional adulteration. Further, FDA developed two draft guidance documents titled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry'' (March 2019) and ''Supplemental Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration'' (February 2020). Once finalized, the draft guidance documents would assist the food industry in developing and implementing the elements of a food defense plan. These guidance documents are available at *https://www.fda.gov/food/food-defense.* All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Description of Respondents: The respondents to this information collection are manufacturers, processors, packers, and holders of retail food products marketed in the United States.

In the **Federal Register** of July 2, 2025, 90 FR 29025, we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. We retain, therefore, our estimate of burden for the information collection, which is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food from very small businesses; § 121.5.	18,080	1	18,080	0.5 (30 minutes)	9,040

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR 121	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Food Defense Plan; § 121.126	3,247	1	3,247	23	74,681
Actionable Process Steps; § 121.130	9,759	1	9,759	20	195,180

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity; 21 CFR 121	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Mitigation Strategies; § 121.135(b)	9,759	1	9,759	20	195,180
Monitoring, Corrective Actions, Verification; §§ 121.140(a), 121.145(a)(1), 121.150(b).	9,759	1	9,759	175	1,707,825
Training; § 121.4	367,203	1	367,203	0.67 (40 minutes)	246,026
Records; §§ 121.305, 121.310	9,759	1	9,759	10	97,590
Total					2,516,482

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

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. 2025–18811 Filed 9–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Initial and Reconciliation Application Forms To Report Graduate Medical Education Data and Full-Time Equivalent Residents Trained by Hospitals Participating in the Children's Hospitals Graduate Medical Education Payment Program; and FTE Resident Assessment Forms To Report FTE Residents Trained by Organizations Participating in the CHGME Payment Program and the Teaching Health Center Graduate Medical Education Program, OMB No. 0915–0247—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than October 29, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to: *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Initial and Reconciliation Application Forms to Report Graduate Medical Education Data and Full-Time Equivalent Residents Trained by Hospitals Participating in the Children's Hospitals Graduate Medical Education Payment Program; and Full-Time Equivalent Resident Assessment Forms to Report Full-Time Equivalent Residents Trained by Organizations Participating in the Children's Hospitals Graduate Medical Education Payment Program and the Teaching Health Center Graduate Medical Education Program, OMB No. 0915–0247—Revision.

Abstract: The Healthcare Research and Quality Act of 1999 (Pub. L. 106–129) established the Children's Hospitals Graduate Medical Education (CHGME) Payment Program, Section 340E of the Public Health Service Act, most recently amended by the Dr. Benjy Frances Brooks Children's Hospital Graduate Medical Education Support Reauthorization Act of 2018 (Pub. L. 115–241). In 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) established the Teaching Health Center Graduate Medical Education (THCGME) Program, Section 340H of the Public Health Service Act. The CHGME Payment Program and the THCGME Program provide federal funding to support graduate medical education programs that train medical and dental residents and fellows. Specifically, the CHGME Payment Program supports residency programs at freestanding children's hospitals that train residents in pediatric, pediatric subspecialty, and non-pediatric care. The THCGME Program supports training for primary care residents/fellows (in family medicine, internal medicine, pediatrics, internal medicine-pediatrics, obstetrics and gynecology, psychiatry, general dentistry, pediatric dentistry, and geriatrics) in community-based ambulatory patient care settings. Children's hospitals and teaching health centers funded by HRSA's CHGME and THCGME programs, respectively, are required to report the number of full-time equivalent (FTE) residents trained during the federal fiscal year. HRSA contracts fiscal intermediaries to assess FTE resident counts reflected in participating children's hospitals' and teaching health centers' applications to determine any changes to the resident FTE counts initially reported. Fiscal intermediaries audit the data reported by the children's hospitals and the teaching health centers and report the verified FTE resident counts to HRSA. Evaluating the data from children's hospitals and teaching health centers ensures compliance with Medicare regulations and HRSA program requirements when determining the number of FTE residents eligible for funding. HRSA plans to submit an ICR because the current OMB clearance for the CHGME Payment Program application and the FTE resident assessment forms and exhibits used by both the CHGME and THCGME programs expire on December 31, 2025. All CHGME Payment Program applications and the FTE resident assessment forms and exhibits used by both the CHGME and THCGME programs are the same as currently approved.