information can be found at *https://www.fda.gov/advisory-committees/psychopharmacologic-drugs-advisory-committee/psychopharmacologic-drugs-advisory-committee-charter* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: June 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12366 Filed 6–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1425]

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, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 July 8, 2022.

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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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—21 CFR Part 121

OMB Control Number 0910–0812—Extension

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act) certain provisions 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 21 CFR part 121 (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);
- 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);
- 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);
- 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 (§ 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);
- 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);
- 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);
- conduct a reanalysis of the food defense plan (§ 121.157);
- ensure that all individuals who perform required food defense activities are qualified to perform their assigned duties (§ 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).

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.

In an effort to reduce burden and assist respondents, FDA offers tools and educational materials related to protecting food from intentional adulteration, including FDA's 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 entitled ''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 entitled ''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 December 17, 2021 (86 FR 71646), 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; 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.

Certain facilities may qualify for an exemption under the regulations. Because these facilities must provide documentation upon request to verify their exempt status, we have characterized this as a reporting burden.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR Section	Number of record-keepers	No. 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
Mitigation Strategies; § 121.135(b)	9,759	1	9,759	20	195,180
Monitoring Corrective Actions, Verification; §§ 121.140(a), 121.145(a)(1), and 121.150(c).	9,759	1	9,759	175	1,707,825
Training;§ 121.160	367,203	1	367,203	0.67 (40 minutes) ..	246,026
Records; §§ 121.305 and 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 other than to increase the burden estimate by 1,224 hours due to a corrected calculation for the estimate related to training (§ 121.160).

Dated: June 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12361 Filed 6–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0482]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drug Applications and Veterinary Master Files

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 July 8, 2022.

ADDRESSES: To ensure that comments on the information collection are received,