members and 37 shall be nonvoting members who serve as representatives of consumer interests and of industry interests. FDA is publishing separate documents announcing the Request for Nominations Notification for Nonvoting Representatives on certain panels of the MDAC. Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The current needs for each panel are listed in table 2. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory panel(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: December 13, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27376 Filed 12–16–21; 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; Proposed Collection; 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, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on collections of information describing mitigation strategies to protect food against intentional adulteration.

DATES: Submit either electronic or written comments on the collection of information by February 15, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 15, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 15, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–1425 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Mitigation Strategies to Protect Food Against Intentional Adulteration.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Mitigation Strategies To Protect Food Against Intentional Adulteration—21 CFR Part 121

OMB Control Number 0910–0812—Extension

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 (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.

In an effort to reduce burden and assist respondents, 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.

We estimate the burden of the information collection 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; 21 CFR 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 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
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: December 10, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27285 Filed 12–16–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0241]

Inspection of Injectable Products for Visible Particulates; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Inspection of Injectable Products for Visible Particulates.'' Visible particulates in injectable products can jeopardize patient safety. This draft guidance addresses the development and implementation of a holistic, risk-based approach to visible particulate control that incorporates product development, manufacturing controls, visual inspection techniques, particulate identification, investigation, and