

nonclinical testing and clinical considerations. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

**III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH guidance documents is available

at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “Implanted Brain-Computer Interface Devices for Patients with Paralysis or Amputation—Nonclinical Testing and Clinical Considerations” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1500045 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
812 ..... “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Investigational Device Exemption ..... Q-submissions .....	0910–0078 0910–0756
801 ..... 820 .....	Medical Device Labeling Regulations ..... Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0485 0910–0073
50, 56 .....	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910–0755

Dated: February 14, 2019.  
**Lowell J. Schiller,**  
*Acting Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2013–N–1425]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Focused Mitigation Strategies To Protect Food Against Intentional Adulteration**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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 April 26, 2019.

**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 April 26, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 26, 2019. 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; Focused 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.

- **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.gpo.gov/fdsys/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.

**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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), 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.

**Focused 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 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 to 121.330).

*Description of Respondents:* The respondents to this information

collection are manufacturers 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 <sup>1</sup>

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

<sup>1</sup> 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. We estimate 18,080 respondents will prepare and update relevant files an

average of 30 minutes annually, for a total annual burden of 9,040 hours (30 minutes × 18,080 firms).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

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).	9,759	1	9,759	175 .....	1,707,825
Training; § 121.160 .....	367,203	1	367,203	0.67 (40 minutes) ...	244,802
Records; § 121.305, § 121.310, .....	9,759	1	9,759	10 .....	97,590
<b>Total</b> .....					<b>2,515,258</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

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 estimated recordkeeping burden associated with these activities totals 2,515,258 annual recordkeeping burden hours and 409,486 annual recordkeeping responses.

We estimate an average of 3,247 firms will continue to need to create a food defense plan under § 121.126, that a one-time burden of 60 hours will be needed to create a plan, and that a burden of 10 hours will be required to update the plan. We annualize this estimate by dividing the total number of burden hours (70) over a 3-year period as reflected in table 2, row 1.

Under § 121.130, each of the estimated 9,759 food production facilities will identify and specify actionable process steps for its food defense plan. We estimate that an individual at the level of an operations

manager incurs a burden of 20 hours for this activity, as reflected in table 2, row 2.

Under § 121.135(b), each of the estimated 9,759 food production facilities must identify and implement mitigation strategies to provide assurances that any significant vulnerability at each step is significantly minimized or prevented, ensuring that the food manufactured, processed, packed, or held by the facility will not be adulterated. We do not specify a specific number or set of mitigation strategies to be implemented. Some of the covered facilities are already implementing mitigation strategies. We estimate that it requires an average of 20 hours per facility to satisfy the recordkeeping burden associated with these activities for a total of 195,180 hours, as reflected in table 2, row 3.

We estimate that the recordkeeping activities associated with monitoring, documenting mitigation strategies, and implementing necessary corrective actions require first-line supervisors or others responsible for quality control an average of 175 hours for each recordkeeping, and that these provisions apply to each of the 9,759 facilities. This

results in a total of 1,707,825 annual burden hours, as reflected in table 2, row 4.

We estimate that recordkeeping activities associated with training under § 121.160 total 244,802 annual burden hours, as reflected in table 2, row 5. We estimate that there are 1.2 million employees working at the regulated facilities and that 30 percent of them (367,203) require training. We estimate that the average burden for the associated recordkeeping activity is approximately 40 minutes (or .67 hours) per record.

Finally, we estimate the 9,759 food production facilities will fulfill the recordkeeping requirements under §§ 121.305 and 121.310, and that it will require an average of 10 hours per record, as reflected in table 2, row 6.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: February 19, 2019.

**Lowell J. Schiller,**  
Acting Associate Commissioner for Policy.

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