0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sau L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2130, Silver Spring, MD 20993–0002, 301–796–2905.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 2019, FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry entitled ''Quality Considerations for Continuous Manufacturing.'' FDA is reopening the comment period until August 12, 2019. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments without compromising the timely publication of the final version of the guidance.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: June 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12292 Filed 6–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–0215; FDA–2012–N–0248; FDA–2015–N–2126; FDA–2012–N–0280; FDA–2012–N–1093; FDA–2018–N–4130; and FDA–2011–N–0143]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Healthcare Professional Survey of Professional Prescription Drug Promotion	0910–0869	4/30/2020
Formal Dispute Resolutions; Appeals Above the Division Level	0910–0430	3/31/2022
Food and Drug Administration's Research and Evaluation Survey for the Public Education Campaign on Tobacco Among LGBT (RESPECT)	0910–0808	3/31/2022
Financial Disclosure by Clinical Investigators	0910–0396	4/30/2022
Food Additive Petitions and Investigational Food Additive Exemptions	0910–0546	4/30/2022
Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water	0910–0658	4/30/2022
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	0910–0752	4/30/2022

Dated: June 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12278 Filed 6–10–19; 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, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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: Fax written comments on the collection of information by July 11, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 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.

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, 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);
- 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.

In the **Federal Register** of February 25, 2019 (84 FR 6009), we published a 60-day notice soliciting public comment of the proposed collections of information. Several comments were received in response to the notice and are summarized here. Minor comments included general support for efforts at protecting food against intentional adulteration. Other comments, however, questioned the estimates we ascribed to meeting the requirements found in subpart C of the applicable regulations: Food defense measures (§§ 121.126 through 121.157 (21 CFR 121.126 through 121.157)). The comments offered alternative estimates ranging from few to several hours, and most correlated this time to aspects of developing plans, conducting vulnerability assessments, and documenting procedures, activities which we attribute to the initial review and implementation of new regulations. We also note that alternative compliance dates were established for the covered entities and have yet to be realized. In addition, to assist respondents in complying with the regulation, including the information collection requirements, we offer both Agency guidance as well as an FDA Food Defense Plan Builder, a user-friendly tool designed to help owners and operators of food facilities develop a personalized food defense plan, which is currently under development with stakeholder input. These and other resources are available from our website at *https://www.fda.gov.* Finally, none of the comments appeared to question the applicability of the recordkeeping or the associated retention requirements found in part 121, subpart D.

While we continue to invite comment regarding our burden estimates, we note that they reflect what we believe is representative of the industry average. This information collection covers numerous respondents with varying facility sizes and with differing product inventories. As compliance with the regulatory requirements continues to take effect, we will continue to evaluate the associated information collection burden accordingly. Although we always appreciate feedback regarding ways to improve efficiencies associated with our information collection activities, we decline to adopt alternative burden estimates for the information collection at this time. Rather, we retain the current estimates, which are 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. 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 [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) and 121.145(a)(1).	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 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.

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 2,516,482 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 § 121.4 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 0.67 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.

Dated: June 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12288 Filed 6–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–6740 and FDA–2017–E–6744]

Determination of Regulatory Review Period for Purposes of Patent Extension; BAXDELA TABLETS—NDA 208610

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period