

regulation for investigational use. Section 409(b) of the FD&C Act (21 U.S.C. 348(b)) specifies the information that must be submitted by a petitioner to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of § 409 of the FD&C Act, we issued procedural regulations under 21 CFR part 571. These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the FD&C Act. The regulations add no substantive requirements to those indicated in the FD&C Act, but attempt to explain these requirements and provide a standard format for submission to speed processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations

contained in 21 CFR parts 501, 573, and 579. The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

With regard to the investigational use of food additives, § 409(j) of the FD&C Act (§ 409(j)) (21 U.S.C. 348(j)) provides that any food additive, or any food bearing or containing such an additive, may be exempted from the requirements of this section if intended solely for investigational use by qualified experts. Investigational use of a food additive is typically to address the safety and/or intended physical or technical effect of the additive.

To implement the provisions of § 409(j), we issued regulations under 21 CFR 570.17. These regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broad

terms by the FD&C Act. Labeling requirements for investigational food additives are also set forth in various regulations contained in 21 CFR 501. The labeling regulations are considered by FDA to be cross-referenced to § 570.17, which is the subject of this same OMB clearance for investigational food additive files.

The information collected is necessary to protect the public health. We use the information submitted by food manufacturers or food additive manufacturers to ascertain whether the data establish the identity of the substance, justify its intended effect in/on the food, and establish that its intended use in/on food is safe.

*Description of Respondents:* Respondents to this collection of information are food manufacturers or food additive manufacturers.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
<i>Food Additive Petitions:</i>					
571.1(c) Moderate Category .....	12	1	12	3,000	36,000
571.1(c) Complex Category .....	12	1	12	10,000	120,000
571.6 Amendment of Petition .....	2	1	2	1,300	2,600
<i>Investigational Food Additive Files:</i>					
570.17 Moderate Category .....	4	1	4	1,500	6,000
570.17 Complex Category .....	5	1	5	5,000	25,000
Total Hours .....					189,600

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

We base our estimate of the total annual responses on submissions received during fiscal years 2016 and 2017. We base our estimate of the hours per response upon our experience with the petition and filing processes.

§ 571.1(c) *Moderate Category:* For a food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 36,000 hours.

§ 571.1(c) *Complex Category:* For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 120,000 hours.

§ 571.6: For a food additive petition amendment, the estimated time requirement per petition is

approximately 1,300 hours. We estimate that, annually, two respondents will each submit one such amendment, for a total of 2,600 hours.

§ 570.17 *Moderate Category:* For an investigational food additive file without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, four respondents will each submit one such file, for a total of 6,000 hours.

§ 570.17 *Complex Category:* For an investigational food additive file with complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. We estimate that, annually, five respondents will each submit one such file, for a total of 25,000 hours.

The burden for this information collected has not changed since the last OMB approval.

Dated: July 24, 2018.

**Leslie Kux,**  
Associate Commissioner for Policy.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-0405]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority**

**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:** Fax written comments on the collection of information by September 4, 2018.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0432. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto: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.

**Medical Device Recall Authority**

*OMB Control Number 0910-0432—Extension*

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and part 810 (21 CFR part 810), mandatory medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death, to: (1) Immediately cease distribution of such device and (2) immediately notify health professionals and device-user facilities of the order

and to instruct such professionals and facilities to cease use of such device.

FDA will then provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be amended to require a mandatory recall of the device.

If, after providing the opportunity for an informal hearing, FDA determines that such an order is necessary, the Agency may amend the order to require a mandatory recall.

FDA issued part 810 to implement the provisions of section 518 of the FD&C Act. The information collected under the mandatory recall authority provisions will be used by FDA to implement mandatory recalls.

In the **Federal Register** of February 22, 2018 (83 FR 7740), 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 <sup>1</sup>

Collection activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Collections Specified in the Order—810.10(d) .....	2	1	2	8	16
Request for Regulatory Hearing—810.11(a) .....	1	1	1	8	8
Written Request for Review—810.12(a)–(b) .....	1	1	1	8	8
Mandatory Recall Strategy—810.14 .....	2	1	2	16	32
Periodic Status Reports—810.16(a)–(b) .....	2	12	24	40	960
Termination Request—810.17(a) .....	2	1	2	8	16
<b>Total Hours</b> .....					<b>1,040</b>

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

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

Collection activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Documentation of Notifications to Recipients—810.15(b) ...	2	1	2	8	16

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Collection activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification to Recipients—810.15(a)–(c) .....	2	1	2	12	24
Notification to Recipients; Follow-up—810.15(d) .....	2	1	2	4	8
Notification of Consignees by Recipients—810.15(e) .....	10	1	10	1	10
<b>Total</b> .....					<b>42</b>

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

The burden estimate has not changed for information collection related to section 518(e) of the FD&C Act and part 810 since the last OMB approval.

Dated: July 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-0270]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types**

**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:** Fax written comments on the collection of information by September 4, 2018.

**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 0910-0799. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, 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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types**

*OMB Control Number 0910-0799—Reinstatement*

**I. Background**

From 1998 to 2008, FDA’s National Retail Food Team conducted a study to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors to foodborne illness outbreaks at the retail level. Specifically, data was collected by FDA specialists in retail and foodservice

establishments at 5-year intervals (1998, 2003, and 2008) to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources,
- Poor Personal Hygiene,
- Inadequate Cooking,
- Improper Holding/Time and Temperature, and
- Contaminated Equipment/Cross-Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods (1998, 2003, and 2008) (Refs. 1 to 3). Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types (Ref. 4).

Using this 10-year survey as a foundation, in 2013 to 2014, FDA initiated a new study in full service and fast food restaurants. This study will span 10 years with additional data collections planned for 2017 to 2018 and 2021 to 2022.

FDA recently completed the baseline data collection in select healthcare, school, and retail food store facility types in 2015 to 2016. This proposed study will also span 10 years with additional data collections planned for 2019 to 2020 (the subject of this information collection request reinstatement) and 2023 to 2024 (which will be posted in the **Federal Register** at the next renewal).

TABLE 1—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY

Facility type	Description
Healthcare Facilities .....	Hospitals and long-term care facilities foodservice operations that prepare meals for highly susceptible populations as defined as follows: <ul style="list-style-type: none"> <li>• Hospitals—A foodservice operation that provides for the nutritional needs of inpatients by preparing meals and transporting them to the patient’s room and/or serving meals in a cafeteria setting (meals in the cafeteria may also be served to hospital staff and visitors).</li> <li>• Long-term care facilities—A foodservice operation that prepares meals for the residents in a group care living setting such as nursing homes and assisted living facilities.</li> </ul> Note: For the purposes of this study, healthcare facilities that do not prepare or serve food to a highly susceptible population, such as mental healthcare facilities, are not included in this facility type category.
Schools (K–12) .....	Foodservice operations that have the primary function of preparing and serving meals for students in one or more grade levels from kindergarten through grade 12. A school foodservice may be part of a public or private institution.
Retail Food Stores .....	Supermarkets and grocery stores that have a deli department/operation as described as follows: <ul style="list-style-type: none"> <li>• Deli department/operation—Areas in a retail food store where foods, such as luncheon meats and cheeses, are sliced for the customers and where sandwiches and salads are prepared onsite or received from a commissary in bulk containers, portioned, and displayed. Parts of deli operations may include:                             <ul style="list-style-type: none"> <li>• Salad bars, pizza stations, and other food bars managed by the deli department manager.</li> <li>• Areas where other foods are cooked or prepared and offered for sale as ready-to-eat and are managed by the deli department manager.</li> </ul> </li> </ul> Data will also be collected in the following areas of a supermarket or grocery store, if present: