VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–04674 Filed 3–5–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types

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 ''Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types.''

DATES: Either electronic or written comments on the collection of information must be submitted by May 6, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 6, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2024–N–0021 for ''Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types.'' 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: 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.*

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.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types

OMB Control Number 0910–0744—Revision

This information collection supports food safety projects administered by FDA. The 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 in retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) in order 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, released in 2000, 2004, and 2009.[1] [2] [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.[4]

Using this 10-year survey as a foundation, FDA initiated a new study in full-service and fast-food restaurants. This study will include data collections completed in 2013–2014 and 2017–2018. An additional collection planned for 2021–2022 was halted due to the COVID–19 pandemic; however, an additional data collection is planned for 2023–2025 (the subject of this information collection request extension). Three data collections are necessary to trend the data.

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

Facility type	Description
Full-Service Restaurants	A restaurant where customers place their orders at their tables, are served their meals at the tables, receive the services of the wait staff, and pay at the end of the meals.
Fast-Food Restaurants	A restaurant that is not a full-service restaurant. This includes restaurants commonly referred to as quick-service restaurants and fast, casual restaurants.

Retail Food Stores	Supermarkets and grocery stores that have a deli department/operation as described as follows:
	• 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:
	  • Salad bars, pizza stations, and other food bars managed by the deli department manager.
	  • Areas where other foods are cooked or prepared and offered for sale as ready-to-eat and are managed by the deli department manager.
	Data will also be collected in the following areas of a supermarket or grocery store, if present:
	• Seafood department/operation—Areas in a retail food store where seafood is cut, prepared, stored, or displayed for sale to the consumer. In retail food stores where the seafood department is combined with another department (e.g., meat), the data collector will only assess the procedures and practices associated with the processing of seafood.
	• Produce department/operation—Areas in a retail food store where produce is cut, prepared, stored, or displayed for sale to the consumer. A produce operation may include salad bars or juice stations that are managed by the produce manager.

The results of this study period will be used to:

- Develop retail food safety initiatives, policies, and targeted intervention strategies focused on controlling foodborne illness risk factors;
- Provide technical assistance to State, local, tribal, and territorial regulatory professionals;
- Identify FDA retail work plan priorities; and
- Inform FDA resource allocation to enhance retail food safety nationwide.

The objectives of this study are to:

[1] FDA, ''Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000).'' Available at *https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf.*

[2] FDA, ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).'' Available at *https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf.*

[3] FDA, ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).'' Available at *https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm.*

[4] FDA National Retail Food Team, ''FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).'' Available at *https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm.*

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in restaurants within the United States;
- Determine the extent to which Food Safety Management Systems and the presence of a Certified Food Protection Manager impact the occurrence of foodborne illness risk factors and food safety behaviors/practices; and
- Determine whether the occurrence of foodborne illness risk factors food safety behaviors/practices in delis differs based on an establishment's risk categorization and status as a single-unit or multiple-unit operation (*e.g.,* restaurants that are part of an operation with two or more units).

A geographical information system database containing a listing of businesses throughout the United States provides the establishment inventory for the data collections. FDA samples establishments from the inventory based on the descriptions in table 1. FDA does not intend to sample operations that handle only prepackaged food items or conduct low-risk food preparation activities. The ''FDA Food Code'' contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation.[5] The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Retail Food Specialists (Specialists) who serve as the data collectors for the study. A standard form is used by the Specialists during each data collection. The form is divided into three sections: Section 1—''Establishment Information''; Section 2—''Regulatory Authority Information''; and Section 3—''Foodborne Illness Risk Factor and Food Safety Management System Assessment.'' The information in Section 1 ''Establishment Information'' of the form is obtained during an interview with the establishment owner or person in charge by the Specialist and includes a standard set of questions. The information in Section 2 ''Regulatory Authority Information'' is obtained during an interview with the program director of the State or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment.

Section 3 includes three parts: Part A for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards; Part B for assessing the food safety management system being implemented by the facility; and Part C for assessing the frequency and extent of food employee handwashing. The information in Part A is collected from the Specialists' direct observations of food employee behaviors and practices. Infrequent, nonstandard questions may be asked by the Specialists if clarification is needed on the food safety procedure or practice being observed. The information in Part B is collected by making direct observations and asking followup questions of facility management to obtain information on the extent to which the food establishment has developed and implemented food safety management systems. The information in Part C is collected by making direct observations of food employee handwashing. No questions are asked in the completion of Section 3, Part C of the form.

FDA collects the following information associated with the establishment's identity: establishment name, street address, city, State, ZIP Code, county, industry segment, and facility type. The establishment-identifying information is collected to ensure the data collections are not duplicative. Other information related to the nature of the operation, such as seating capacity and number of employees per shift, is also collected.

The burden associated with the completion of Sections 1 and 3 of Form FDA 3967 is specific to the persons in charge of the selected facilities. The burden includes the time it will take the person in charge to accompany the data collector during the site visit and answer the data collector's questions. The burden related to the completion of Section 2 of the form is specific to the program directors (or designated individuals) of the respective regulatory authorities. This burden includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA has collaborated with the Food Protection and Defense Institute to develop a web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. This platform is accessible to State, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study. FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Fast-Food Restaurants—Completion of Sections 1 and 3	400	1	400	1.36	544
Full-Service Restaurants—Completion of Sections 1 and 3	400	1	400	1.73	692
Fast-Food and Full-Service Restaurants—Completion of Section 2	800	1	800	0.5 (30 minutes)	400
Retail Food Stores—Completion of Form FDA 3967, Sections 1 and 3	400	1	400	3	1,200
Retail Food Stores—Completion of Form FDA 3967, Section 2	400	1	400	0.5 (30 minutes)	200
Entry Refusals—All Facility Types	24	1	24	0.08 (5 minutes)	2
Total					3,038

[1] There are no capital costs of 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 adjustments to our burden estimate. On our own initiative, however, and for efficiency of Agency operations, we are revising the information collection to include and consolidate related information collection found in 0910–0799. Therefore, our estimated burden for the information collection reflects an increase of 1,401 total burden hours and a corresponding increase of 808 total annual responses.

[5] FDA, ''FDA Food Code.'' Available at *https://www.fda.gov/FoodCode.*

Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04722 Filed 3–5–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Food and Drug Administration Approval to Market a New Drug

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: Submit written comments (including recommendations) on the collection of information by April 5, 2024.

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 0910–0001. 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.

Applications for FDA Approval To Market a New Drug—21 CFR Part 314

OMB Control Number 0910–0001—Revision

This information collection supports implementation of statutory and regulatory authorities that govern new drugs. Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States unless an approval of an application filed with FDA under section 505(b) or (j) of the FD&C Act is effective with respect to such drug. We have issued regulations in part 314 (21 CFR part 314) that establish procedures and requirements for applications submitted in accordance with section 505 of the FD&C Act. The regulations in subpart A (§§ 314.1 through 314.3) set forth general provisions, while regulations in subparts B and C (§§ 314.50 through 314.99) set forth content and format requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) respectively. The regulations include requirements for the submission of specific data elements along with patent information, pediatric use information, supplements and amendments, proposed labeling, and specific postmarketing reports (PMRs). Respondents to the information collection are sponsors of these applications.

Regulations in subpart D (§§ 314.100 through 314.170) explain Agency actions on applications and set forth timeframes for FDA review. The information collection includes provisions established through our Agency user fee programs, most recently authorized under the FDA User Fee Reauthorization Act of 2022. These provisions pertain to performance goals, expedited programs, review transparency, communications with FDA, dispute resolution, drug safety enhancements, and the allocation of Agency resources to align with these program objectives as agreed to with our stakeholders and set forth in our ''User Fee Performance Goals for Fiscal Years 2023–2027'' Commitment Letters, which are available from our website at *https://www.fda.gov* along with more information about specific FDA user fee programs.

Included among the provisions in subpart G (§§ 314.410 through 314.445), § 314.420 covers information to include in drug master files (DMFs). To assist respondents to this information collection we have prepared templates, guidance, forms, and resources available from our website at *https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.* We have developed Form FDA 3938 and accompanying instructions on submitting DMFs in accordance with the applicable regulations. We are revising Form FDA 3898 and the accompanying instructions to allow for multiple selections of submission types and to clarify the number of digits to be entered for the holder and establishment registration numbers.

In accordance with § 314.445, we also develop Agency guidance documents to assist respondents in complying with provisions in part 314. These guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115. To search available FDA guidance documents, visit our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Applications submitted in accordance with subpart H (§§ 314.500 through 314.560) pertain to accelerated approval of new drugs for serious or life-threatening illnesses.

Information collection and associated burden for the submissions in subpart I (§§ 314.600 through 314.650) pertain to approval of certain new drugs when human efficacy studies are not ethical or feasible. The regulations provide for the submission of specific data elements, animal studies of safety and efficacy to establish likely clinical benefit in humans and upon approval of the drug product, additional requirements and/or restrictions to ensure safe use of the product. Additional PMRs, safety reporting, and promotional material as well as requirements for withdrawal of these human drug applications, and FDA termination of requirements for these human drug applications are included in §§ 314.620 through 314.650. The estimated burden for these human drug applications is included in the reported submissions and burden under general human drug applications, § 314.50, and other specific regulations in the table for human drug application requirements in general.

Finally, we are also revising the collection to include the submission of information pursuant to the CREATES Act (enacted as part of the Further Consolidated Appropriations Act of 2020 (21 U.S.C. 355–1(1) and 355–2)). Under the CREATES Act, developers of potential drug and biological products are enabled to use the CREATES pathway to obtain samples of brand products that are needed to support their applications. Relevant products include those submitted in generic drug applications under section 505(j) of the FD&C Act and NDAs submitted under