hazards to which they may be exposed; (2) Relative symptoms and appropriate emergency treatment; and (3) Proper conditions and precautions for safe use and exposure.

B. Annual Reporting Burden

Respondents: 563.
Responses per Respondent: 3.
Hours per Response: .658.
Total Burden Hours: 1111.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat, 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace, in all correspondence.

Dated: June 11, 2012.

Joseph A. Neurauter,

Director, Office of Acquisition Policy, Senior Procurement Executive.

[FR Doc. 2012–14836 Filed 6–18–12; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Coordinating Center for Research and Training to Promote the Health of People with Developmental and Other Disabilities, FOA DD12–006, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 11:00 a.m.–3:00 p.m., July 10, 2012 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Coordinating Center for Research and Training to Promote the Health of People with Developmental and Other Disabilities, FOA DD12–006, initial review.''

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F–46, Atlanta, Georgia 30341, Telephone: (770) 488–3585.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 13, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–14922 Filed 6–18–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0547]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013–2022)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey entitled ''Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013–2022).''

DATES: Submit written or electronic comments on the collection of information by August 20, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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 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 Retail and Foodservice Facility Types (2013–2022)—(OMB Control Number 0910–NEW)

I. Background

In 1998, the U.S. Food and Drug Administration's National Retail Food Team initiated a 10-year voluntary survey 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 (CDC) as contributing factors to foodborne illness outbreaks at the retail level. Specifically, the survey included data collection inspections of various types

of 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.
- Contaminated Equipment/Protection from Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods (1998, 2003, and 2008) (Refs. 1–3). 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).

The research obtained from these studies provides FDA a solid foundation for developing a national retail food program model that can be used by Federal, state, local, and tribal agencies to:

- Identify essential food safety program performance measurements;
- Assess strengths and gaps in the design, structure, and delivery of program services;
- Establish program priorities and intervention strategies focused on reducing the occurrence of foodborne illness risk factors; and
- Create a mechanism that justifies program resources and allocates them to program areas that will provide the most significant public health benefits.

Using this 10-year survey as a foundation, FDA is proposing to conduct a new voluntary survey encompassing annual data collections over a 10-year period. The survey will determine the following for each facility type included in the study:

- The foodborne illness risk factors that are in most need of priority attention during each data collection period;
- Trends of improvement or regression in foodborne illness risk factor occurrence over time; and
- The impact of industry food safety management systems in controlling the occurrence of foodborne illness risk factors.

The results of the proposed study will be used to:

- Formulate Agency retail food safety policies and initiatives;
- Identify retail food work plan priorities and allocate resources to enhance retail food safety nationwide;
- Generate nationally representative estimates of the prevalence of foodborne illness risk factors and trends of improvement and regression over time; and
- Recommend best practices and targeted intervention strategies to assist the retail and foodservice industry and state, local, and tribal regulators with reducing foodborne illness risk factors.

The statutory basis for FDA conducting this survey is the Public Health Service Act (the PHS Act) (42 U.S.C. 243, section 311(a)) (Also 21 CFR 5.10(a)(2) and (4)), which requires that FDA provide assistance to state and local governments relative to the prevention and suppression of communicable diseases. In addition, the PHS Act requires that FDA cooperate with and aid state and local authorities in the enforcement of their health regulations and provide advice on matters relating to the preservation and improvement of public health. Additionally, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) and Economy Act (31 U.S.C. 1535) require that FDA provide assistance to other Federal, state, and local governmental bodies.

In 2012, FDA will conduct a pilot data collection to practice the use of the data collection form and methods and test exportation of the pilot data into a central repository. Following the pilot, the Agency plans to conduct annual data collections beginning in 2013 with the initial data collection for select restaurant facility types, followed by the initial data collection for select institutional foodservice facility types in 2014 and select retail food store facility types in 2015. The results of the initial data collection for each of the facility types will serve as the baseline measurement from which trends will be analyzed. Two additional data collection periods for each of the facility types are planned at 3-year intervals after the initial data collection for purposes of analyzing trends.

TABLE 1—SUMMARY OF DATA COLLECTION TIME FRAMES [1]

Industry segment	Facility types included in the survey	Year for initial data collection (baseline measurement)	Second data collection period	Third and final data collection period
Restaurants	Full Service Restaurants Fast Food Restaurants	2013	2016	2019
Institutional Foodservice	Hospitals Nursing Homes Elementary Schools (K–6)	2014	2017	2020
Retail Food Stores	Deli Departments/Stores Meat and Poultry Departments/Markets Seafood Departments/Markets Produce Departments/Markets	2015	2018	2021

[1] Data collections for each of the facility types within an industry segment will be conducted using a 3-year interval period. Initial data collection will serve as the baseline. Subsequent collections will provide the data needed to analyze trends.

A description of the facility types included in the proposed survey is included in table 2:

TABLE 2—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY

Industry segment	Facility type	Description
Restaurants	Full Service Restaurants.	Establishments where customers place their order at their table, are served their meal at the table, receive the service of the wait staff, and pay at the end of the meal.

TABLE 2—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY—Continued

Industry segment	Facility type	Description
	Fast Food Restaurants	Also referred to as quick service restaurants and defined as any restaurant that is not a full service restaurant.
Institutional Foodservice	Hospitals	Foodservice operations that serve patients, staff, and hospital visitors in a traditional hospital setting. Individuals who are acutely ill to those who are immunocompromised are a target population for data collection.
	Nursing Homes	Foodservice operations that serve highly susceptible populations living in a group care setting. The elderly (55+ years) is the target population for the data collection. Also includes assisted living facilities.
	Elementary Schools (K–6).	Foodservice operations that serve students from one or more grade levels from preschool through Grade 5. Young children are a target population for the data collection.
Retail Food Stores	Deli Departments/ Stores.	Departments in retail food stores where potentially hazardous foods (time/temperature control for safety foods) such as luncheon meats and cheeses are sliced for the customer and where sandwiches and salads are prepared onsite or received from a commissary in bulk containers, portioned, and displayed. Freestanding cheese shops are categorized as delis. Parts of the deli may also include: • Salad bars and other food bars maintained by the deli department manager; • Areas where meat or poultry are cooked and offered for sale as ready-to-eat; • Pizza stands; and • Limited bakery operations attached to or adjacent the deli.
	Meat and Poultry Departments/Markets.	Meat and poultry departments in a retail food store, as well as any freestanding meat market or butcher shop that sells raw meat or poultry directly to the consumer.
	Seafood Departments/ Markets.	Seafood departments in retail food stores and freestanding seafood markets that sell seafood directly to the consumer including the preparation and sale of raw and/or ready-to-eat seafood. In-store sushi bars are considered part of the seafood department for the purposes of the data collection.
	Produce Departments/ Markets.	Areas or departments where produce is cut, prepared, stored, or displayed. A produce department may include salad bars that are managed by the produce manager, as well as juicers.

A geographical information system database containing a listing of businesses throughout the United States will be used as the establishment inventory for the data collections. FDA's Center for Food Safety and Applied Nutrition (CFSAN) Biostatistical Branch, in collaboration with the FDA National Retail Food Team, will perform a series of filtering processes of the various database food establishment categories to ensure establishments are correctly classified and considered eligible to participate in the survey based on the descriptions in table 2.

To further determine the pool of establishments eligible for selection, an effort will be made to exclude 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 (Ref. 5). The vast majority of selected establishments are to be chosen from risk categories 2 through 4.

FDA has approximately 25 Regional Retail Food Specialists (Specialists) who will serve as the data collectors for the 10-year study. The Specialists are geographically dispersed throughout the United States and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types to be surveyed. The Specialists are also standardized by FDA's CFSAN personnel in the application and interpretation of the FDA Model Food Code (Ref. 5). The geographical distribution of Specialists throughout the United States allows for a broad sampling of facility types in all regions of the United States; therefore, establishments will be randomly selected to participate in the study from among all eligible establishments located within a 150-mile radius of each of the Specialists' home locations.

The pilot will include approximately 4 data collection inspections for each of the approximately 25 Specialists, or a total of 100 inspections. In order to obtain a sufficient number of observations to conduct statistically significant analysis, the FDA CFSAN Biostatistical Branch has determined, based on the previous 10-year foodborne illness risk factor study that was performed, that approximately 400 data collection inspections of each facility type are needed during the initial and subsequent data collection periods. The sample for each data collection period will be evenly distributed among Specialists. Given that participation in the study by industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments will be selected for each Specialist for cases where the restaurant facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists will contact the state or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist will verify with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist will also ascertain whether the selected facility is under legal notice from the state or local regulatory authority. If the selected facility is under legal notice, the Specialist will not conduct a data collection, and a substitute establishment will be used. An invitation will be extended to the state or local regulatory authority to accompany the Specialist on the data collection visit.

A standard data collection form will be used by the Specialists during each inspection. 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. Section 3 includes three parts (parts A–C) for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards (part A);

the industry food safety management being implemented by the facility (part B); and the frequency of food employee hand washing (part C).

The information in Section 1—Establishment Information of the form will be obtained during an interview with the establishment owner or person in charge by the Specialist and will include a standard set of questions. The information in Section 2—Regulatory Authority Information will be 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, part A will be 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. For Section 3, part B of the form, Specialists will make direct observations and ask follow up questions of industry management to obtain information on the extent to which the food establishments have developed and implemented food safety management systems. Section 3, part C of the form will involve direct observations of hand washing frequency by the Specialists. No questions will be asked in the completion of this part of the form.

Due to the infrequent and nonstandard nature of the questions that may or may not be asked to clarify direct observations made by the Specialists in completing Section 3, parts A and C of the data collection form, only the burden associated with the information collection related to the completion of Sections 1 and 2 and Section 3, part B of the form is included in burden estimates. For each data collection, the respondents will include the person in charge of the selected facility and the program director of the respective regulatory authority. For the pilot, 25 Specialists will conduct 4 data collection inspections; thus, FDA estimates the number of respondents to be 200 (25 Specialists × 4 data collection inspections × 2 respondents per data collection). The estimate of the hours per response is based on its previous experience with collecting similar information in previous data collection efforts. We estimate that it will take each of the respondents 15 minutes (0.25 hours) to answer the questions related to Sections 1 and 2 and Section 3, part B of the form, for a total of 50 hours. FDA bases its estimate of the number of respondents during the subsequent activities (data collections) on 400 inspections being conducted in each facility type. FDA CFSAN's Biostatistical Branch has determined that 400 inspections are necessary to provide the sufficient number of observations needed to conduct a statistically significant analysis of the data. The data collections in the Restaurant Segment will occur in 2013, 2016, and 2019, and will each consist of 1,600 respondents. We estimate that it will take each respondent 15 minutes (0.25 hours) to answer the questions related to Sections 1 and 2 and Section 3, part B of the form, for a total of 400 hours. The data collections in the Institutional Foodservice Segment will occur in 2014, 2017, and 2020, and will each consist of 2,400 respondents. We estimate that it will take each respondent 15 minutes (0.25 hours) to answer the questions related to Sections 1 and 2 and Section 3, part B of the form, for a total of 600 hours. The data collections in the Retail Food Store Segment will occur in 2015, 2018, and 2021, and will each consist of 3,200 respondents. We estimate that it will take a respondent 15 minutes (0.25 hours) to answer the questions related to Sections 1 and 2 and Section 3, part B of the form, for a total of 800 hours. Thus, the total estimated burden is 5,450 hours.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
2012 Pilot Data Collection to Practice Use of Form and Methods and Exportation of Data Into Central Repository	200	1	200	0.25 (15 minutes)	50
2013 Baseline Data Collection—Restaurant Segment (includes two facility types)	1,600	1	1,600	0.25 (15 minutes)	400
2014 Baseline Data Collection—Institutional Foodservice Segment (includes three facility types)	2,400	1	2,400	0.25 (15 minutes)	600
2015 Baseline Data Collection—Retail Food Store Segment (includes four facility types)	3,200	1	3,200	0.25 (15 minutes)	800
2016 Second Data Collection—Restaurant Segment (includes two facility types)	1,600	1	1,600	0.25 (15 minutes)	400
2017 Second Data Collection—Institutional Foodservice Segment (includes three facility types)	2,400	1	2,400	0.25 (15 minutes)	600
2018 Second Data Collection—Retail Food Store Segment (includes four facility types)	3,200	1	3,200	0.25 (15 minutes)	800
2019 Third and Final Data Collection—Restaurant Segment (includes two facility types)	1,600	1	1,600	0.25 (15 minutes)	400
2020 Third and Final Data Collection—Institutional Foodservice Segment (includes three facility types)	2,400	1	2,400	0.25 (15 minutes)	600
2021 Third and Final Data Collection—Retail Food Store Segment (includes four facility types)	3,200	1	3,200	0.25 (15 minutes)	800

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					5,450

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Report of the FDA Retail Food Program Steering Committee. *Database of Foodborne Illness Risk Factors* (2000). Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm123546.pdf.*

2. *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types* (2004). Available at: *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm089696.htm.*

3. *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types* (2009). Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224682.pdf.*

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: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224152.pdf.*

5. FDA Model Food Code. Available at: *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.htm.*

Dated: June 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14850 Filed 6–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 26, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31–2417, Silver Spring, MD 20993–0002, (301) 796–9001, Fax: (301) 847–8533, email: *DODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 26, 2012, during the morning session, the committee will discuss a supplement to biologics license application (BLA) 125156 for LUCENTIS (ranibizumab) injection by Genentech, Inc., for the treatment of diabetic macular edema (DME). Ranibizumab injection is currently approved for the treatment of neovascular (wet) age-related macular degeneration (AMD) and macular edema following retinal vein occlusion (RVO).

During the afternoon session, the committee will discuss new biologics license application (BLA) 125422, ocriplasmin intravitreal injection (proposed tradename, Jetrea) by ThromboGenics, Inc., indicated for the treatment of symptomatic vitreomacular adhesions (sVMA) including macular hole.

FDA intends to make background materials available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 13, 2012. Oral presentations from the public will be scheduled between approximately 10