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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Hong Vu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5345, Silver Spring, MD 20993–0002, 301–796–7401.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model.'' The emergence of concomitant trials for multiple investigational drug products for the treatment of rare disease can pose significant challenges to effective drug development, given the limited number of patients worldwide with these diagnoses. This guidance discusses, among other things, a multi-arm, multi-company clinical trial as a novel approach to enhance the efficiency of drug development in pediatric rare diseases using pediatric Gaucher disease as an example. The proposal applies only to systemic (*i.e.,* non-neurological) manifestations of Gaucher disease (*i.e.,* patients with Type I and Type III phenotypes).

The purpose of this guidance is to facilitate drug development in pediatric rare diseases, with a focus on Gaucher disease. In this guidance, Gaucher disease is provided as a disease model. However, the principles underlying this proposal may be extended to other areas of drug development in rare diseases. The guidance was originally a document developed as a strategic collaboration between FDA and the European Medicines Agency to enhance the efficiency of drug development in Gaucher disease, which was released in 2014 for public comment. The draft guidance is an updated version of the document and has no fundamental changes to the original intent and content.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model.'' 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.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR 201.57 for the content and format of prescription drug labeling was approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 1, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26357 Filed 12–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Safety Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, 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 January 8, 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 0910–0345. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Safety Survey

OMB Control Number 0910–0345—Extension

Under section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), we are authorized

to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. The Food Safety Survey measures consumers' knowledge, attitudes, and beliefs about food safety. Previous versions of the survey were collected in 1988, 1993, 1998, 2001, 2006, 2010, and 2016. Food Safety Survey data are used to measure trends in consumer food safety habits including hand and cutting board washing, cooking practices, and use of food thermometers. Data are also used to evaluate educational messages and to inform policymakers about consumer attitudes about technologies such as food irradiation and biotechnology.

The proposed Food Safety Survey will contain many of the same questions and topics as previous Food Safety Surveys to facilitate measuring trends in food safety knowledge, attitudes, and behaviors over time. The proposed survey will also be updated to explore emerging consumer food safety topics and expand understanding of previously asked topics.

The methods for the proposed Food Safety Survey will be largely the same as those used with the previous Food Safety Surveys with the exception of the inclusion of address based sampling (ABS) methods to explore the method as a possible alternative for new survey questions. ABS is sampling from address frames that are usually based, in part, on residential addresses in the U.S. Postal Service Computerized Delivery Sequence File. ABS is a cost effective method of sampling that provides much coverage of U.S. households for in-person, mail, telephone, and multimode surveys (including web-based surveys.) The Food Safety Survey will continue to include cell phones in addition to landlines for the telephone interviews. A nationally representative sample of 4,000 adults will be selected at random to complete the survey. The survey will also include an oversample of Hispanics and Blacks to ensure a minimum of 400 each. Additionally, methods will be employed to test for the presence of response bias. Participation in the survey will be voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

In the **Federal Register** of July 3, 2017 (82 FR 30871), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received two comments. One commenter discussed the importance of food safety, for which FDA agrees, and one commenter provided a comment which was unrelated to the information collection. After evaluating these comments, FDA will not revise the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Cognitive interview	9	1	9	1	9
Pretest screener	45	1	45	0.0167 (1 minute)	1
Pretest	18	1	18	0.33 (20 minutes)	6
Survey screener	10,000	1	10,000	0.0167 (1 minute)	167
Survey	4,000	1	4,000	0.33 (20 minutes)	1,320
Non-response survey screener	125	1	125	0.0167 (1 minute)	2
Non-response survey	50	1	50	0.167 (10 minutes)	8
Total					1,519

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

FDA's burden estimate is based on the Agency's prior experience with the Food Safety Survey. FDA estimates that the burden hours for this information collection will remain the same since the last OMB approval.

Dated: December 1, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26356 Filed 12–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01).

Date: January 9, 2018.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Jay R. Radke, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3G11B, National Institutes of Health, NIAID, 5601 Fishers Lane MSC–9823, Bethesda, MD 20892–9823, (240) 669–5046, *jay.radke@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 1, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–26324 Filed 12–6–17; 8:45 am]

BILLING CODE 4140–01–P