and toolkits for LHDs and community groups so that they can align their efforts and strengthen the benefits and positive impacts of citizen science activities. For interviews, the information collection will target citizen scientists and end users of citizen science data.

Citizen science is defined as research activities (*e.g.,* data collection, analysis, and reporting) performed by members of the general public without any particular training in science. Citizen science is growing in popularity, fueled in part by growing use of smartphones and other personal devices in the population. Although citizen collection and use of data during disasters has increased exponentially in recent years and there is great policy interest in the phenomenon, there has been no robust research to date on the use of, barriers to, and impact of citizen science in disasters. Local health departments (LHDs) lack tools to respond to and coordinate with citizen science activities within communities. Furthermore, citizen science organizations lack information on how to organize their activities for ultimate impact.

This is an exploratory study and is the first of its kind to explore the growing phenomenon of disaster citizen science. Disaster citizen science is a rapidly growing field that is the focus of policy interest, but currently devoid of research. This study will generate information that can help define the phenomenon of disaster citizen science and may result in nationally representative baseline data that can support changes in citizen science awareness, barriers, and activities.

While interviews will be hypothesis generating and provide rich data on the experiences with citizen science to date across all stakeholders active in this enterprise, the nationally-representative survey data will allow us to generalize findings to the full population of LHDs in the U.S.

CDC will collaborate with a contractor to implement this project. Researchers will target citizen scientists and their partners (*e.g.,* academics who work with citizen scientists on research projects) and LHDs in a position to use citizen science data to inform public health decision-making. For interviews, researchers will sample for maximum variation, seeking to obtain variation on U.S. region, type and sophistication of citizen science project, type of disaster encountered, and previous experience with disaster citizen science.

The researchers aim to conduct 35–55 individual and group facilitated semi-structured interviews, each lasting approximately 60 minutes, to cover topics including benefits and uses of citizen science, barriers to and facilitators of citizen science, and strengths and limitations of citizen science activities and resources. Researchers will identify potential interview participants through literature reviews and snowball sampling in a phased approach starting with citizen science and LHD organizations. Researchers will sample for maximum variation in order to capture the full range of citizen scientist and health department experiences on this topic.

For the survey, the researchers will target a nationally representative sample of 600 local health officials and will apply survey weights to ensure that findings have external validity and can be generalized to LHDs in the U.S. The survey, which will take 30 minutes to complete, will include questions on both citizen science as applied to disaster preparedness and response, and citizen science as occurring in other contexts (such as environmental health)to draw lessons for preparedness and response.

OPHPR anticipates that the knowledge resulting from this research project will contribute significantly to the evidence base for preparedness and response and lead to improved efficiency, effectiveness, and outcomes in several domains.

Participation in this study is voluntary. There are no costs to respondents other than their time. A summary of annualized burden hours is below.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Citizen scientists and their partners; local health officials.	Interview Guide (semi-structured questionnaire).	55	1	75/60	69
Local health departments	Survey	300	1	30/60	150
Total					219

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–19824 Filed 9–18–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0192]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of United States Manufacturers/Processors With Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products to China

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 the information collection provisions found in the

guidance entitled ''Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China: Guidance for Industry.''

DATES: Submit either electronic or written comments on the collection of information by November 20, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 20, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 20, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2014–N–0192 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting CFSAN-Regulated Products to China.'' 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 Office between 9 a.m. and 4 p.m., Monday through Friday.

- 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.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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@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, 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.

Establishing and Maintaining Lists of U.S. Manufacturers/Processors With Interest in Exporting CFSAN-Regulated Products to China—21 U.S.C. 371

OMB Control Number 0910–0839—Extension

The United States exports a large volume and variety of foods in international trade. For certain food products, foreign governments may require assurances from the responsible authority of the country of origin of an imported food product that the manufacturer/processor of the food

product is in compliance with applicable country of origin regulatory requirements. Some foreign governments establish additional requirements with which exporters are required to comply.

In August 2011, China's State General Administration of the People's Republic of China for Quality Supervision, Inspection, and Quarantine (AQSIQ) published the ''Administrative Measures for Registration of Overseas Manufacturers,'' known as AQSIQ Decree 145 (*https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Registration%20of%20Overseas%20Food%20Manufacturing%20Facilities%20_Beijing_China%20-%20Peoples%20Republic%20of_6-27-2012.pdf*), which became effective May 1, 2012. AQSIQ Decree 145, among other requirements, mandates that foreign competent authorities provide the Certification and Accreditation Administration of China (CNCA) with a name list of overseas manufacturers of imported food applying for registration with CNCA for each commodity that CNCA has deemed to require registration. As of June 2017, milk and milk products, seafood, infant formula, and formula for young children are among the commodities for which CNCA requires registration of overseas manufacturers under AQSIQ Decree 145. CNCA has recognized FDA/Center for Food Safety and Applied Nutrition (CFSAN) as the competent food safety authority in the United States to establish and maintain lists of U.S. establishments that intend to export U.S. milk and milk products, seafood, infant formula, and/or formula for young children to China, including the corresponding products manufactured by each establishment and intended for export to China. In order to implement AQSIQ Decree 145, FDA and CNCA entered into a Memorandum of Understanding (China MOU) on June 15, 2017, which sets out the two agencies' intent to facilitate the conditions under which U.S. manufacturers/processors can export to China milk and milk products, seafood, infant formula, and/or formula for young children.

Under the China MOU, FDA intends to establish and maintain lists that identify U.S. manufacturers/processors that have expressed interest to FDA in exporting milk and milk products, seafood, infant formula, and/or formula for young children to China; are subject to our jurisdiction; and have been found by FDA to be in good regulatory standing with FDA, including a finding by FDA that, during the most recent facility inspection, the manufacturers/processors have been found to be in substantial compliance with all applicable FDA regulations, including, but not limited to, current good manufacturing practice requirements for the identified products for export to China. Further, the China MOU provides for FDA to receive evidence that the manufacturer/processor has been certified by a third-party certification body—as acknowledged by CNCA—to meet the relevant standards, laws, and regulations of China for the identified food products for export to China. On June 28, 2017, FDA issued a guidance document entitled, ''Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China: Guidance for Industry'' which can be found at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm378777.htm.* The guidance informs industry of information that FDA and CNCA will collect to manage the listing of these manufacturers/processors and foods for export to China pursuant to AQSIQ Decree 145 and the China MOU.

In accordance with 5 CFR 1320.13, FDA requested emergency review and approval of the collections of information found in the guidance document. The routine course of approval would have delayed our ability to collect the information from firms and, thus, would have been disruptive in our efforts to facilitate exports of food in compliance with requirements established by China in AQSIQ Decree 145. OMB granted the approval under emergency clearance procedures on June 27, 2017.

FDA uses the information submitted by manufacturers/processors to consider them for inclusion on FDA's lists of eligible manufacturers/processors that may ship food products to China, which we maintain. Updates to the FDA lists are sent to CNCA, which publishes quarterly its version of the information in the FDA lists on China's Web site (*http://english.cnca.gov.cn/*). The purpose of the lists is to assist China in its determination of which U.S. milk and milk product, seafood, infant formula, or formula for young children manufacturers/processors are eligible to import these products into China under applicable Chinese law. Currently FDA maintains lists for milk and milk product, seafood, infant formula, and formula for young children but FDA wants to be prepared if CNCA requires listing of manufacturers/processors of other CFSAN-regulated products in the future. As such, the information collection request is not limited to milk and milk product, seafood, infant formula, and formula for young children but also may include other CFSAN-regulated products.

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
New written requests to be placed on the lists	370	1	370	1	370
Third-party certification	370	1	370	21	7,770
Biennial update	555	1	555	1	555
Third-party certification biennial update	555	1	555	21	11,655
Occasional updates	100	1	100	0.5	50
Total					20,400

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

The burden for this information collection has not changed since the last OMB approval. Based on our experience maintaining other export lists, we estimate that, annually, an average of 370 new manufacturers/processors will submit written requests to be placed on the China lists. The estimate of the number of hours that it will take a

manufacturer/processor to gather the information needed to be placed on a list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily available to manufacturers/processors. We estimate that a firm will require 1 hour to read the guidance, gather the information needed, and prepare a communication to FDA that contains the information needed to request that the manufacturer/processor be placed on a list.

To be placed on a list, manufacturers/processors should provide FDA with evidence that they have obtained third-party certification from a CNCA-acknowledged certifier that the manufacturer/processor complies with the standards, laws, and regulations of China according to relevant requirements specified in AQSIQ Decree 145. Based on our experience with other certification programs, FDA estimates that it will take each new manufacturer/processor about 21 hours to complete the third-party certification process for a total of 7,770 burden hours (370 manufacturers/processors × 21 hours).

Under the guidance, every 2 years each manufacturer/processor on the lists must provide updated information in order to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, or 555 manufacturers/processors (1,110 manufacturers/processors × 0.5 = 555), will resubmit the information to remain on the lists. We estimate that a manufacturer/processor already on the lists will require 1 hour to biennially update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA, for a total of 555 hours.

During the biennial update, manufacturers/processors also need to be recertified by a third-party certifier to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, 555 manufacturers/processors (1,110 manufacturers/processors × 0.5 = 555), will get recertified. We estimate that it will take each manufacturer/processor about 21 hours to complete the certification process for a total of 11,655 burden hours (555 manufacturers/processors × 21 hours).

FDA expects that, each year, approximately 100 manufacturers/processors will need to submit an occasional update and each manufacturer/processor will require 0.5 hours to prepare a communication to FDA reporting the change, for a total of 50 hours.

Dated: September 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19890 Filed 9–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0932]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Warning Statements for Cigarette Graphic Health Warnings

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 October 19, 2017.

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–NEW and title ''Experimental Study on Warning Statements for Cigarette Graphic Health Warnings.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonalynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Experimental Study on Warning Statements for Cigarette Graphic Health Warnings

OMB Control Number 0910–NEW

The health risks associated with the use of cigarettes can be significant and far-reaching. In 2009, Congress enacted the Tobacco Control Act (TCA) (Pub. L. 111–31), which amends the Federal Food, Drug, and Cosmetic Act to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amends section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require FDA to issue ''regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1).'' Section 202(b) of the Tobacco Control Act further amends section 4 of the FCLAA by adding that the Secretary, through notice and comment rulemaking, may adjust the ''text of any of the label requirements . . . . if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.''

In the **Federal Register** of June 22, 2011 (76 FR 36628), FDA issued a final rule entitled ''Required Warnings for Cigarette Packages and Advertisements,'' which specified nine images to accompany new textual warning statements for cigarettes. Although the rule was scheduled to become effective 15 months after it issued, a panel of the U.S. Court of Appeals of the District of Columbia held, on August 24, 2012, that the rule in its current form violated the First Amendment. In a letter to Congress on March 15, 2013, the Attorney General reported FDA's intention to undertake research to support a new rulemaking consistent with the Tobacco Control Act. Preliminary research has been underway since 2013. Informed by the previous court decisions on this matter, including on the First Amendment, the next phase of the research includes the study proposed here, which is an effort by FDA to collect data concerning revised textual warning statements for use with new images as part of cigarette graphic health warnings, and their potential impact on public understanding of the risks associated with the use of cigarettes.

As currently proposed, this Experimental Study on Warning Statements for Cigarette Graphic Health Warnings is a voluntary online