Agency's docket. After considering any comments received, the Agency will resubmit the proposed collection of information to OMB. Thus, FDA is withdrawing the proposed collection of information published on December 29, 2011, at this time.

Dated: May 22, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13142 Filed 5–30–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0145]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

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 July 2, 2012.

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 ''Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities.'' Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities—(OMB Control Number 0910–New)

The Food Safety Modernization Act (FSMA) (Pub. L. 111–353) states in section 205(c)2 that a review must be conducted to assess the State and local government capacities to show needs for enhancement in the areas of staffing levels, laboratory capacities, and information technology systems. This mandate is referenced again in FSMA section 110, stating that a review of current food safety and food defense capabilities must be presented to Congress no later than 2 years after the date of enactment (enactment date January 4, 2011). In order to facilitate this review, a survey will be distributed to State and local health and agriculture agencies. Results of the survey will be used to analyze the gaps and trends in capacity that occurs at the State and local government levels. Results of the analyses will enable FSMA partners to develop strategies to enhance food safety and food defense capacity. In developing these strategies, FDA will be able to work with other Federal, State and local Agencies to improve and expand food safety and defense to ultimately reach a state of an integrated food safety system.

The survey will be conducted electronically, which allows FDA to conduct streamlined analysis while creating a low-burden, user-friendly environment for respondents to complete the survey. Once the results have been tabulated, a report will be generated and given to the FSMA section 110 work group to present to Congress as well as the FSMA section 205(c)1 work group to develop strategies to leverage and enhance current State and local capacities.

In the **Federal Register** of February 24, 2012 (77 FR 11132), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received six comments. The comments, and the Agency's responses, are discussed in the following paragraphs.

(Comment 1) FDA conducted a review of existing surveys.

(Response) Although helpful, these surveys did not fully address factors such as laboratory capacity and information technology in State and local agencies. Therefore, this survey will be used to fill the gaps of various other surveys so that FDA can meet its objective as congressionally mandated in FSMA.

(Comment 2) The proposed information collection is necessary for the proper performance of FDA's functions.

(Response) FDA believes that this comment does not address the proposed information collection.

(Comment 3) The National Association of County and City Health Officials (NACCHO) recommends FDA builds upon information gathered from existing food safety and defense assessments and surveys.

(Response) Prior to developing this survey, FDA conducted a systematic review of current and past surveys conducted by Federal, State, and local Agencies, academia, industry, and associations such as the Association of Food and Drug Officials (AFDO), the Association of State and Territorial Health Officials, and NACCHO's 2008 survey regarding budget cuts and reductions of State and local agencies. This review revealed that the current and past surveys did not contain sufficient information for FDA to establish and analyze possible gaps in the areas of food safety, food defense, laboratories, and information technology. The results of the review of current and past surveys were conveyed to an FDA working group focused on drafting a report to Congress that is specified by FSMA section 110. Under section 110, FDA has a congressionally mandated deadline to conduct a more extensive review by January 4, 2013, which will require the support of section 205(c)2. FDA was aware that NACCHO was conducting a survey but due to time restrictions, FDA could not wait for NACCHO's survey to be made public prior to developing the current survey. Also, FDA did not know the content of NACCHO's survey and how it would address the needs of obtaining information to support FSMA section 205(c)2.

(Comment 4) FDA should survey 1,400 State and local agencies at minimum instead of focusing on 1,400 State and local employees.

(Response) FDA is proposing to survey 1,400 State and local agencies. The involvement of single or multiple individuals from a single agency will be left to the discretion of the responding entity.

(Comment 5) NACCHO recommends that the assessment be designed to allow multiple employees within an agency access to the survey on multiple occasions to fully and accurately complete the survey.

(Response) FDA has an arrangement with AFDO, through a cooperative agreement, to deliver the survey, but at this time, the exact mechanism for

delivering the survey has not been established. FDA will take into consideration NACCHO's suggestion of developing a Web-based portal with log in capability to allow multiple users to log in to the same survey to increase the efficiency of completing the survey. In addition, hardcopies of the survey can be made available upon request.

(Comment 6) The assessment should be conducted on a routine basis.

(Response) FDA agrees with NACCHO in its statement that a survey, such as this one, should be conducted on a more regular basis to track and trend gaps. At this time, this survey is intended to be a one-time collection of information. FDA could consider conducting future surveys, depending on Agency resources and priorities.

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
Current State and local government agencies	1,400	1	1,400	1	1,400

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

This survey isslated to be a one-time survey. Through testing on six FDA employees who were former State employees, the survey development team has concluded that it should take no longer than 1 hour for the 1,400 current State and local government agencies to complete the survey. FDA is requesting this data collection burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: May 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13140 Filed 5–30–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0146]

Guidance for Industry on Irritable Bowel Syndrome—Clinical Evaluation of Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Irritable Bowel Syndrome—Clinical Evaluation of Drugs for Treatment.'' This guidance is intended to assist the pharmaceutical industry and investigators who are developing drugs for the treatment of irritable bowel syndrome (IBS), specifically the IBS indications for IBS with diarrhea (IBS–D) and IBS with constipation (IBS–C). The guidance describes the evolution of patient-reported outcome (PRO) measures as primary endpoints for IBS clinical trials, and sets forth provisional endpoints and trial design recommendations that sponsors may apply to IBS clinical trials as PRO measurements continue to evolve. The guidance also discusses the future development of IBS PRO instruments. This guidance finalizes the draft guidance published in March 2010.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ruyi He, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5122, Silver Spring, MD 20993–0002, 301–796–0910.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Irritable Bowel Syndrome—Clinical Evaluation of Drugs for Treatment.'' This guidance is intended to assist the pharmaceutical industry and investigators who are developing drugs for the treatment of IBS. This guidance applies to the IBS indications for IBS–D and IBS–C.

A well-defined and reliable PRO instrument that measures the clinically important signs and symptoms associated with each IBS subtype would be the ideal primary efficacy assessment tool in clinical trials used to support labeling claims, but at this time such an instrument is not available. We recognize that it will take some time to develop adequate instruments and that in the meantime there is a great need to develop effective therapies for patients with IBS. Therefore, until the appropriate PRO instruments have been developed, sponsors should consider the provisional endpoints and trial design recommendations set forth in the guidance.

This guidance was published as a draft guidance in March 2010. Changes made to the guidance took into consideration written and verbal comments received. In addition to editorial changes primarily for clarification, the major changes are as follows:

- The section on trial design was modified by adding a randomized withdrawal design to address the need for maintenance treatment to prevent sign or symptom recurrence.
- The section on trial endpoints was modified to note that a drug can be specifically developed to treat only one of two major signs or symptoms of IBS (abnormal defecation or abdominal pain). Demonstration of significant and clinically meaningful changes in the targeted single endpoint could serve as a basis for approval, as long as the other important symptom or sign has not worsened on treatment.
- Trial entry criteria for IBS–D were modified to allow more IBS–D patients to participate in IBS clinical trials, and the definition of a responder to treatments for IBS–D was modified accordingly.
- Definitions of a responder for abdominal pain alone, constipation, and diarrhea were added.