NE., MS–D74, Atlanta, Georgia 30333; comments may also be sent by e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarify of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

LRN Special Data Calls—Existing Collection in Use Without an OMB Control Number—National Center for Emerging and Zoonotic Infectious Diseases (proposed) (NCEZID, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. The LRN's mission is to maintain an integrated national and international network of laboratories that can respond to acts of biological, chemical, or radiological terrorism and other public health emergencies. Federal, state and local public health laboratories voluntarily join the LRN.

The LRN Program Office maintains a database of information for each member laboratory that includes contact information as well as staff and equipment inventories. However, semiannually or during emergency response the LRN Program Office may conduct a Special Data Call to obtain additional information from LRN Member Laboratories in regards to biological or chemical terrorism preparedness. Special Data Calls may be conducted via queries that are distributed by broadcast emails or by survey tools (*i.e.* Survey Monkey). This is a request for a generic clearance. The only cost to respondents is their time to respond to the data call.

Estimate of Annualized Burden Hours

Forms	Number of respondents	Average number of responses per respondent	Average burden per response (hours)	Total burden hours
Special Data Call	200	4	30/60	400

Dated: June 10, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–14625 Filed 6–16–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0279]

Center for Drug Evaluation and Research Data Standards Plan; Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of the draft document entitled "CDER Data Standards Plan Version 1.0" (draft plan). The draft plan outlines the general approach proposed for development of a comprehensive data standards program in the Center for Drug Evaluation and Research (CDER). The draft plan identifies key objectives for a data standards program at CDER, processes to be developed to ensure successful use of those standardized data, and a set of recommended projects to begin in calendar year (CY) 2010.

DATES: Submit either electronic or written comments on the draft plan by September 15, 2010.

ADDRESSES: Submit written requests for single copies of the draft plan 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 draft plan.

Submit electronic comments on the draft plan 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: Ranjit Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1166, Silver Spring, MD 20993–0002, e-mail: *Ranjit.Thomas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA receives an enormous and growing amount of data in regulatory submissions in a variety of formats from many sources. This wealth of data holds great potential to advance CDER's regulatory and scientific work, but the present lack of standardized data creates significant challenges to realizing that potential. A data standards plan would enhance CDER's ability to efficiently and effectively perform its critical public health mission.

At present, the lack of standardized data affects CDER's review processes by curtailing a reviewer's ability to perform integral tasks such as rapid acquisition, analysis, storage, and reporting of regulatory data. Standardized data will allow reviewers to increase review consistency and perform evaluations across the drug lifecycle. Improved data quality, accessibility, and predictability will give reviewers more time to carry out complex analyses, ask in-depth questions, and address late-emerging issues.

Standardization of data submissions, a requirement for electronic submissions, and a robust computational infrastructure would make significant improvements possible. Facilitating improvements requires careful analysis, advanced planning, project management, expert input, and effective communication among all key stakeholders. To be successful, a plan is required to identify, develop, adopt, and maintain data standards that meet CDER "end user" needs.

FDA is making available for public comment the draft plan entitled "CDER

Data Standards Plan Version 1.0." The draft plan is intended to communicate FDA's approach for establishing a comprehensive data standards program at CDER and ensuring the development and successful use of data standards for all key data needed to make regulatory decisions. FDA will consider comments received in developing future versions of the plan.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov* or http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM214120.pdf.

Dated: June 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–14637 Filed 6–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–N–0284 and FDA–2009–D–0461]

Risk Evaluation and Mitigation Strategies; Notice of Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 2-day public meeting to obtain input on issues and challenges associated with the development and implementation of risk evaluation and mitigation strategies (REMS) for drugs and biological products. As FDA has taken steps to implement the REMS provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), some stakeholders have raised concerns about the impact of various REMS, and the growing number of REMS on the health care system, as well as on individual prescribers, pharmacists, distributors, and other affected stakeholders. To obtain public input about the REMS program and its impact, and to gather additional input on a draft guidance for industry issued on October 1, 2009 entitled "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications," FDA has decided to hold this public meeting. FDA wishes to give a wide range of stakeholders the opportunity to provide input in this area, and will take the information it obtains from the meeting into account in its implementation of the REMS program and in the development of the final guidance and future REMS guidances.

DATES: The meeting will be held on July 27 and 28, 2010, from 8:30 a.m. to 4:30 p.m. Individuals who wish to present at the meeting must register by July 6, 2010. The comment period for the draft guidance for industry on "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications" has been reopened until August 31, 2010.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify each set of comments with the corresponding docket number for either the public meeting or the draft guidance as follows: Docket No. FDA–2010–N–0284, "Risk Assessment and Mitigation Strategies; Public Meeting," and Docket No. FDA–2009–D–0461, Draft guidance for industry on "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications."

FOR FURTHER INFORMATION CONTACT: Kristen Everett, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 6228, Silver Spring, MD 20993, 301–796–0453, FAX: 301–847–8440, Email: *REMSpublicmeeting@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85). Title IX, subtitle A, section 901 of FDAAA created new section 505–1 of the FDCA, which authorizes FDA to require persons submitting new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for prescription products, or biologics license applications (BLAs), to submit and implement a REMS if FDA determines that a REMS is necessary to ensure the benefits of a drug outweigh the risks of the drug. To require a REMS for an already approved drug, FDA must have new safety information as defined in the statute.

FDAAA specifies the criteria FDA must consider in determining when to require a REMS, the elements of a REMS that FDA must and may require, and additional considerations when requiring a REMS with elements to assure safe use. FDAAA also contains provisions that are specifically directed to REMS for ANDAs and describes enforcement actions for failure to comply with REMS. FDAAA contains provisions that require the FDA to seek input from patients, physicians, pharmacists, and other health care providers about how the elements to assure safe use may be standardized to (1) not be unduly burdensome on patient access to the drug and (2) to the extent practicable, minimize the burden on the health care delivery system. A webinar will be available on the agency's Web site at *http://www.fda.gov/Drugs/NewsEvents/ucm210201.htm* 2 weeks before the meeting, describing in more detail the statutory requirements for REMS.

II. REMS Draft Guidance and Comment Period

FDA has been implementing the REMS FDAAA provisions for more than 2 years. On October 1, 2009, the Agency published in the **Federal Register** (74 FR 80801) a notice of availability of a draft guidance for industry entitled, "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications." Although comments on Agency guidances are welcome at any time (see 21 CFR 10.115(g)(5)), to ensure that comments could be considered as the Agency worked on the final version of the guidance, interested persons were invited to comment on the draft guidance by December 30, 2009. The draft guidance provides information