contract with FDA, capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment as described in the MDUFA III Commitment Letter. For Phase 1, FDA will award the contract no later than the end of the second quarter of FY2013. Findings on high-priority recommendations (i.e., those likely to have a significant impact on review times) will be published within 6 months of award; final comprehensive findings and recommendations will be published within 1 year of contract award. FDA will publish an implementation plan within 6 months of receipt of each set of recommendations. For Phase 2 of the independent assessment, the contractor will evaluate the implementation of recommendations and publish a written assessment no later than February 1, 2016.

The assessment will address FDA's premarket review process using an assessment framework that draws from appropriate quality system standards, including, but not limited to, management responsibility, document controls and records management, and corrective and preventive action.

The assessment will include, but not be limited to, the following areas:

1. Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

2. Analysis of elements of the review process (including the presubmission process, and investigational device exemption, premarket notification (510(k)), and premarket approval application reviews) that consume or save time to facilitate a more efficient process. This includes analysis of root causes for inefficiencies that may affect review performance and total time to decision. This will also include recommended actions to correct any failures to meet MDUFA goals. Analysis of the review process will include the impact of combination products, companion diagnostic products, and laboratory developed tests on the review process.

3. Assessment of FDA methods and controls for collecting and reporting information on premarket review process resource use and performance.

4. Assessment of effectiveness of FDA's Reviewer Training Program implementation.

5. Recommendations for ongoing periodic assessments and any additional, more detailed or focused assessments.

FDA will incorporate findings and recommendations, as appropriate, into its management of the premarket review program. FDA will analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and assure its effectiveness. FDA also will incorporate the results of the assessment into a Good Review Management Practices (GRMP) guidance document. FDA's implementation of the GRMP guidance will include initial and ongoing training of FDA staff, and periodic audits of compliance with the guidance.

FDA is seeking public comment now on the proposed statement of work for the assessment, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM331516.pdf.*

III. Comments

Interested persons may submit either written comments regarding the statement of work to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: December 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30511 Filed 12–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1168]

Draft Guidance for Industry on Providing Submissions in Electronic Format—Summary Level Clinical Site Data for Center for Drug Evaluation and Research's Inspection Planning; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Submissions in Electronic Format—Summary Level Clinical Site Data for CDER's Inspection Planning.'' The draft guidance is intended to assist applicants in the voluntary submission of a clinical dataset that describes and summarizes the characteristics and outcomes of clinical investigations at the level of the individual study site (summary level clinical site dataset). The summary level clinical site dataset is intended to facilitate use of a risk-based approach to timely identification of clinical investigator sites for onsite inspection by FDA during the review of marketing applications. This draft guidance describes a recommended electronic format for the summary level clinical site dataset to be submitted voluntarily in new drug applications (NDAs), biologics licensing applications (BLAs), and NDA and BLA supplemental applications submitted to FDA's Center for Drug Evaluation and Research (CDER).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 19, 2013.

ADDRESSES: 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, 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 guidance document.

Submit electronic comments on the draft 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: Paul Okwesili, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5353, Silver Spring, MD 20993–0002, 301–796–0173.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Submissions in Electronic Format—Summary Level Clinical Site Data for CDER's Inspection Planning.'' FDA is responsible for making regulatory decisions about drugs and

biological products after reviewing clinical safety and efficacy data submitted in support of NDAs, BLAs, and NDA and BLA supplements submitted to CDER (BLAs submitted to and reviewed by CDER as described in the **Federal Register** of June 26, 2003 (68 FR 38067), available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/UCM186799.pdf*). CDER's Bioresearch Monitoring Program has specific responsibility for verifying the integrity of data submitted to FDA in support of new NDAs and BLAs and supplements, and for determining whether clinical trials are conducted in compliance with applicable FDA regulations and statutory requirements, including those intended to ensure the rights and welfare of human research subjects.

A. Site Inspections

As part of the application review process, FDA may conduct onsite inspections of clinical investigators, sponsors, contract research organizations, and institutional review boards. The study-related information in applications is critical to FDA's selection of clinical investigator sites for inspection. However, the current submission format for the data does not facilitate efficient site selection. Thus, CDER is requesting submission of a structured, summary-level clinical site dataset.

B. Summary Level Clinical Site Dataset

CDER recently initiated a pilot program evaluating a risk-based model for selecting clinical investigators for inspection. This model permits evaluation of an array of risk parameters across clinical investigator sites associated with marketing applications.

The summary level clinical site dataset:

- Contains data from all relevant studies used to support evaluation of the application, including studies supportive of various treatment indications; and
- Presents the characteristics and outcomes of the study at the site level.

The data requested in the summary level clinical site dataset comprise data elements currently collected under regulations in 21 CFR part 312 and maintained, tabulated, and submitted under regulations in 21 CFR part 314, specifically § 314.50(d)(5) *Clinical data section* and § 314.50(f) *Case report forms and tabulations* or in 21 CFR part 601, specifically § 601.2 *Applications for biologic licenses; procedures for filing*.

The electronic submission of a summary level clinical site dataset is intended to facilitate FDA's timely selection of clinical investigator sites for inspection to evaluate the integrity of the data submitted in the application or supplement.

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 Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments regarding to *http://www.regulations.gov*. It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov*.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 that 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** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance recommends an electronic format for a summary level clinical site dataset to be submitted voluntarily in NDAs, BLAs, and NDA and BLA supplemental applications submitted to CDER. The summary level clinical site dataset is intended to facilitate use of a risk-based approach to timely identification of clinical investigator sites for on-site inspection by FDA during the review of marketing applications.

The summary level dataset comprises information required in parts 312, 314, or 601, including case histories (§ 312.62(b)), information regarding foreign clinical studies not conducted under an investigational new drug application (IND) (§ 312.120), and the clinical data section (§ 314.50(d)(5)) and case report forms and tabulations (§ 314.50(f)), or in part 601 (§ 601.2 *Applications for biologic licenses; procedures for filing*) in an NDA, BLA, or supplement. The draft guidance recommends that the data be submitted electronically in a format that will facilitate site selection. The variables described in the format are elements currently used in other submissions; some of the variable names are new. The financial disclosure information is currently reported in Module 1 (region specific information) of the electronic common technical document, but is new as a variable in a dataset. In addition, identifying that a study has been conducted under an IND is new as a request in a dataset. Initial preparation of the summary level clinical site dataset and the development of new standard operating procedures (SOPs) would require additional time. Once SOPs have been established, generation of the dataset should not involve significant additional work. The applicant would likely perform additional quality assurance, which may add time to preparation and review of the submission.

Based on CDER's data on the number of applications, including supplements, that would be covered by the draft guidance, we estimate that each year approximately 75 applicants will voluntarily submit for 96 applications the summary level clinical site dataset in electronic format as recommended by

the draft guidance. We estimate that the submission of each summary level clinical site dataset will take approximately 26 hours to prepare.

Initial preparation of the summary level clinical site dataset would involve the development of new SOPs for the preparation of the summary level clinical site dataset. We estimate that 75 applicants would take approximately 12 hours to develop and subsequently 1 hour annually to maintain and update the SOP(s). The summary level clinical site dataset submitted with each application would likely involve additional quality assurance procedures, which would add approximately 1 hour for each submission.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 312 have been approved under OMB control number 0910–0014; the collections of information in part 314 have been approved under OMB control number 0910–0001.

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

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Activity	Number of respondents (i.e. applicants)	Number of responses per respondent (i.e., applications)	Total responses	Hours per response	Total hours
Summary Level Clinical Site Dataset Submissions	75	1.3	96	26	2,496
Dataset Quality Assurance	75	1.3	96	1	96
Total					2,592

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total records	Hours per recordkeeper	Total hours
Develop Initial SOP(s)	75	1	75	12	900
Maintain and Update SOP(s)	75	1	75	1	75
Total					975

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

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: December 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30510 Filed 12–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0548]

Drug Safety and Risk Management 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. This meeting is being rescheduled due to the postponement of the October 29–30, 2012, Drug Safety and Risk Management Advisory Committee meeting due to unanticipated weather conditions caused by Hurricane Sandy.

Name of Committee: Drug Safety and Risk Management 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 January 24, 2013, from 8 a.m. to 6 p.m., and January 25, 2013, from 8 a.m. to 5 p.m. This meeting is a reschedule of a postponed meeting announced in the **Federal Register** of June 8, 2012 (77 FR 34051–34052), originally scheduled for October 29–30, 2012.

ADDRESSES: FDA has opened a docket for public comment on this meeting. The docket number is FDA–2012–N–0548. The docket opened for public comment on June 8, 2012. The docket will close on February 1, 2013. Interested persons may submit either electronic or written comments regarding this meeting. Submit electronic comments 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. All comments received will be posted without change, including any personal information provided. It is only necessary to send one set of 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. Comments received on or before January 9, 2013, will be provided to the committee before the meeting. Any comments received for the originally scheduled October 29 and 30, 2012, Drug Safety and Risk Management Advisory Committee meeting will be provided to the committee. It is not necessary to resubmit any comments previously submitted to the docket. If a comment originally submitted to the docket is resubmitted prior to January 9, 2013, both comments will be provided to the committee.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD, 20993–