TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Type of respondent | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Requests to Issue an EUA or a Substantive Amendment to an Existing EUA | 9 | 1.33 | 12 | 33 | 396 |
| FDA Review of a Pre-EUA Package or an Amendment Thereto | 11 | 1.45 | 16 | 35 | 560 |
| Manufacturers of an Unapproved EUA Product | 5 | 1.6 | 8 | 2 | 16 |
| Public Health Authorities; Unapproved EUA Product | 30 | 3 | 90 | 2 | 180 |
| Total | | | | | 1,152 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Type of respondent | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Manufacturers of an Unapproved EUA Product | 5 | 1.6 | 8 | 25 | 200 |
| Public Health Authorities; Unapproved EUA Product | 30 | 3 | 90 | 3 | 270 |
| Total | | | | | 470 |

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

Dated: *December 13, 2012.*

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–30513 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–1202]**

### Comprehensive Assessment of the Process for the Review of Device Submissions; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the statement of work for an assessment of the process for the review of medical device submissions. The assessment is part of the FDA performance commitments relating to the Medical Device User Fee Amendments of 2012 (MDUFA III), which reauthorized device user fees for fiscal years 2013–2017. The assessment is described in section V, ''Independent Assessment of Review Process Management'', of the commitment letter entitled ''MDUFA Performance Goals and Procedures'' [1] (MDUFA III Commitment Letter). The assessment will be conducted by an independent contractor in two phases. FDA is providing a period of 30 days for public comment on the statement of work before requesting proposals for the assessment.

**DATES:** Submit electronic or written comments by February 4, 2013.

**ADDRESSES:** 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 should be identified with the docket number found in brackets in the heading of this document. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sligar, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3291, Silver Spring, MD 20993–0002, 301–796–9384, *Amber.Sligar@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA).[2] Title II of FDASIA is MDUFA III, which gives FDA the authority to collect device user fees from industry for fiscal years (FYs) 2013 to 2017. MDUFA III took effect on October 1, 2012, and will sunset in 5 years on October 1, 2017.

Device user fees were first established by Congress in 2002. Medical device companies pay fees to FDA when they register their establishment and list their devices with the Agency, whenever they submit an application or a notification to market a new medical device in the United States, and for certain other types of submissions. Under MDUFA III, FDA is authorized to collect user fees that will total approximately $595 million (plus adjustments for inflation) over 5 years. With this additional funding, FDA will be able to hire more than 200 full-time-equivalent workers over the course of MDUFA III. In exchange, FDA has committed to meet certain performance goals outlined in the MDUFA III Commitment Letter.

## II. Assessment of FDA's Process for the Review of Device Submissions

Section V of the MDUFA III Commitment Letter states that FDA and the device industry will participate in a comprehensive assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry. The assessment will be conducted in two phases by a private, independent consulting firm, under

[1] *http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.*

[2] *http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.*

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