

injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA. We estimate that it will take respondents 0.35 hours annually to report the information.

In the **Federal Register** of May 07, 2015 (80 FR 26278), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. However, since the 60-day notice, we have updated the burden

estimates to reflect revisions made by the final rule, “Medical Device Reporting: Electronic Submission Requirements,” which became effective August 14, 2015. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemptions—803.19 .....	.....	56	4	224	1	224
User Facility Reporting—803.30 and 803.32 .....	.....	520	7	3,640	0.35	1,274
User Facility Annual Reporting—803.33 Importer Reporting, Death and Serious Injury—803.40 and 803.42 .....	3419 .....	520	1	520	1	520
Manufacturer Reporting—803.50, through 803.53 .....	.....	1,240	204	252,960	0.10	25,296
Supplemental Reports—803.56 .....	.....	1,050	94	98,700	0.10	9,870
<b>Total</b> .....	.....	.....	.....	.....	.....	37,185

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
MDR Procedures—803.17 .....	1,820	1	1,820	3.3	6,006
MDR Files—803.18 .....	1,820	1	1,820	1.5	2,730
<b>Total</b> .....	.....	.....	.....	.....	47,200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Importer Reporting, Malfunctions—803.40 and 803.42 .....	60	25	1,500	0.35	525

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 20, 2015.  
**Leslie Kux**,  
*Associate Commissioner for Policy.*  
 [FR Doc. 2015-21036 Filed 8-25-15; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-D-2537]

**Request for Quality Metrics; Notice of Draft Guidance Availability and Public Meeting; Request for Comments; Extension of Comment Period**

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

**ACTION:** Notice of draft guidance availability and public meeting; request for comments; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the comment period for the notice of draft guidance availability and public meeting that appeared in the **Federal Register** of July 28, 2015, and August 7, 2015. In the notice of draft guidance availability and public meeting, FDA requested comments on a number of specific questions identified in the document. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the notice of draft guidance

availability and public meeting published July 28, 2015 (80 FR 44973) and August 7, 2015 (80 FR 47493). Submit either electronic or written comments by November 27, 2015.

**ADDRESSES:** You may submit comments by any of the following methods:

**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

**Written Submissions**

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Instructions:** All submissions received must include the Docket No. (FDA–2015–D–2537) for this notice of draft guidance availability and public meeting. 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 “Request for Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Lesley DeRenzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5161, Silver Spring, MD 20993–0002, 240–402–4612.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of July 28, 2015, and August 7, 2015, FDA published a notice of draft guidance availability and public meeting with a 60-day comment period and requested comments on a number of specific questions identified throughout the document. Comments on the notice of draft guidance availability and public meeting will inform FDA’s development and planned implementation of a quality metrics program launched under the authority of the Federal Food, Drug, and Cosmetic Act.

FDA is extending the comment period for an additional 60 days, until November 27, 2015. The Agency believes that an additional 60-day extension of the comment period for the notice of draft guidance availability and public meeting will allow adequate time for interested persons to submit comments without significantly delaying Agency decisionmaking on these important issues.

##### **II. Request for Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your

comments to identify the specific questions or topic to which they refer. 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: August 21, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA–2015–N–2919]**

#### **In Vitro Diagnostic Testing for Direct Oral Anticoagulants; Public Workshop; Request for Comments**

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

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled “In Vitro Diagnostic Testing for Direct Oral Anticoagulants”. The objective of the workshop is to gain public input and to discuss analytical performance requirements for the diagnostic assessment of direct oral anticoagulants (DOACs) and the clinical circumstances under which patients receiving these agents would require testing. Specifically, this workshop aims to do the following: (1) Evaluate the impact of DOACs on traditional coagulation testing results; (2) identify clinical circumstances where testing of DOACs anticoagulant activity or concentration would be relevant; (3) discuss clinically meaningful interpretation of coagulation testing results for patients on DOACs; and (4) review the regulatory requirements for granting clearance for in vitro diagnostic devices intended for coagulation testing in patients treated with DOACs.

**Date and Time:** The public workshop will be held on October 26, 2015, from 9 a.m. to 5 p.m.

**Location:** The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is

through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

**Contact Person:** Claudia Dollins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66 Rm. 5262, Silver Spring, MD 20993–0002, 301–796–4807, [Claudia.Dollins@fda.hhs.gov](mailto:Claudia.Dollins@fda.hhs.gov).

**Registration:** Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., October 16, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

**Contact for Special Accommodations:** If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication and Education, 301–796–5661, [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) no later than October 9, 2015.

To register for the public workshop, please visit FDA’s Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see *Contact for Special Accommodations*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

**Streaming Webcast of the Public Workshop:** This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by October 16, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 20, 2015. If you have never attended a Connect Pro