FEE SCHEDULE FOR EACH VESSEL SIZE

Vessel size (GRT [1])	Inspection fee
Extra Small (<3,000 GRT)	US$1,495
Small (3,001–15,000 GRT) ..	2,990
Medium (15,001–30,000 GRT)	5,980
Large (30,001–60,000 GRT)	8,970
Extra Large (60,001–120,000 GRT)	11,960
Mega (>120,001 GRT)	17,940

[1] Gross register tonnage in cubic feet, as shown in Lloyd's Register of Shipping.

Dated: August 19, 2015.

Pamela J. Cox,

Director, Division of the Executive Secretariat, Office of the Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2015–21107 Filed 8–25–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: State Self-Assessment Review and Report.

OMB No.: 0970–0223.

Description: Section 454(15)(A) of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, requires each State to annually assess the performance of its child support enforcement program in accordance with standards specified by the Secretary of the Department of Health and Human Services, and to provide a report of the findings to the Secretary. This information is required to determine if States are complying with Federal child support mandates and providing the best services possible. The report is also intended to be used as a management tool to help States evaluate their programs and assess performance.

Respondents: State Child Support Enforcement Agencies or the Department/Agency/Bureau responsible for Child Support Enforcement in each State.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-assessment report	54	1	4	216

Estimated Total Annual Burden Hours: 216.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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 practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity 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 automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–21053 Filed 8–25–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0110]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting

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 September 25, 2015.

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 0910–0437. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting (21 CFR Part 803)—(OMB Control Number 0910–0437)—Revision

Section 519(a)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)

(21 U.S.C. 360i(a)(1)) requires every manufacturer or importer to report whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury or has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Section 519(b)(1)(A) of the FD&C Act requires whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death or serious illness, of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary of HHS and, if the identity of the manufacturer is known, to the manufacturer of the device.

Section 519(b)(1)(B) of the FD&C Act requires whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility, shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary of HHS if the identity of the manufacturer is not known.

Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems. Information from these reports will be used to evaluate risks associated with medical devices which will enable FDA to take appropriate regulatory measures in protection of the public health under section 519 of the FD&C Act. Thus FDA is requesting approval for these information collection requirements which are being implemented under part 803 (21 CFR part 803).

Respondents to this collection of information are businesses or other for-profit and nonprofit organizations including user facilities, manufacturers, and importers of medical devices.

Part 803 requires user facilities to report to the device manufacturer and to FDA in case of a death, incidents where a medical device caused or contributed to a death or serious injury. Additionally, user facilities are required to annually submit the number and summary of adverse events reported during the calendar year using Form FDA 3419. Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way, that should the malfunction recur, it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA.

The number of respondents for each Code of Federal Regulations (CFR) section in table 1 is based upon the number of respondents entered into FDA's internal databases. FDA estimates, based on its experience and interaction with the medical device community, that all reporting CFR sections are expected to take 1 hour to complete, with the exception of § 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required for reporting the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The Agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the medical device reporting (MDR) requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints under § 803.18(d).

The Agency has estimated that on average 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures under § 803.17 to be 6,006 hours (1,820 respondents × 3.3 hours). For those entities, a one-time burden of 3.3 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Under § 803.18, 1,820 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1.5 hours to complete the recordkeeping requirement for this section. Total hours for this section equal 2,730 hours.

Reporting Requirements

Part 803 requires user facilities to report incidents where a medical device caused or contributed a death or serious injury to the device manufacturer and to FDA in the case of a death. Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way that, should the malfunction recur, it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers (see third-party disclosure burden table), unless the manufacturers are unknown, then the reports are sent to FDA.

FDA estimates are based on our experience and interaction with the medical device community and burden analysis from the rulemaking. Section 803.19 is expected to take approximately 1 hour to complete, but is only required to report the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

Recordkeeping Requirements

The Agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the MDR requirements as part of their internal quality control system. The Agency has estimated that on average, 1,820 user facilities, importers, and manufacturers would annually be required, under § 803.17, to establish new procedures, or revise existing procedures, in order to comply with this provision. We estimate that it will take each respondent 3.3 hours annually to establish new procedures, or revise existing procedures. We estimate that it will take each respondent 1.5 hours annually to maintain the records.

Third-Party Disclosure Burden

Under §§ 803.40 and 803.42, device importers report deaths and serious

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 [1]

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	3419	520	1	520	1	520
Importer Reporting, Death and Serious Injury—803.40 and 803.42		1	1	1	1	1
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
Total						37,185

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

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
Total					47,200

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

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

[1] 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