ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–9 Annual Survey of Refugees	2,000	1	0.63	1,253.20
Request for Participation Letter	2,000	1	0.04	80

Estimated Total Annual Burden Hours: 1,333.20

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7245, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: May 14, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–11606 Filed 5–18–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0075]

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 (the PRA).

DATES: Fax written comments on the collection of information by June 18, 2009.

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: 202–395–6974, or e-mailed 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: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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)—Extension

Section 519(a)(1) of Federal Food, Drug, and Cosmetic Act (the 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: (A) May have caused or contributed to a death or serious injury, or (B) 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 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 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 and, if the identity of the manufacturer is known, to the manufacturer of the device.''

Section 519(b)(1)(B) of the act requires ''whenever a device user facility receives or otherwise becomes aware of: (i) 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 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 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.

In the **Federal Register** of February 25, 2009 (74 FR 8547), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one non-related PRA comment that did not require a response.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.19		57	4	228	3.0	684
803.30 and 803.32		393	2	777	1.0	777
803.33	3,419	393	1	393	1	393
803.40 and 803.42		73	37	2,682	1.0	2,682
803.50 and 803.52		1,601	104	166,271	1.0	166,271
803.56		1,200	63	76,186	1.0	76,186
Total				246,537		246,993

[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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
803.17	220	1	220	10	2,200
803.18(a) through (d)	30,000	1	30,000	1.5	45,000
Total					47,200

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

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 FDA Form 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 of this document 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 2,200 hours (220 respondents x 10 hours). For those entities, a one-time burden of 10 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, 30,000 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 45,000 hours.

Dated: May 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–11625 Filed 5–18–09; 8:45 am]

BILLING CODE 4160–01–S