year. The NEW program report provides information on the activities and accomplishments of grantees' NEW programs. The NEW program report and instructions specify the program data that NEW grantees report annually.

Respondents

Federally recognized Indian Tribes and Tribal organizations that are NEW program grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
NEW program plan guidance	26	1	29	754
NEW program report	48	1	15	720

Estimated Total Annual Burden Hours: 1,474.

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 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. 2012–13812 Filed 6–6–12; 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 July 9, 2012.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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)—Extension

Section 519(a)(1) of the Federal Food, Drug, and Cosmetic Act (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: (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 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 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: (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 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 advents 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 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 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 × 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.

In the **Federal Register** of February 14, 2012 (77 FR 8260), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Subsequent to publication of the 60-day notice, FDA performed an additional inspection of the data and consulted with the MDR program staff. Per this extra review, FDA has updated the estimated burden hours to more accurately reflect the burden.

Reporting Requirements

21 CFR 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, 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 21 CFR 803.19. Section 803.19 is expected to take approximately 3 hours 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. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints under 21 CFR 803.18(d). We estimate that it will take each respondent 1.5 hours annually to maintain the records.

The agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required, under 21 CFR 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 10 hours annually to establish new procedures, or revise existing procedures.

Third-Party Disclosure Burden

Under 21 CFR 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 1 hour annually to report the information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

CFR Section	FDA Form No.	Number of respondents	Annual frequency of response	Total annual responses	Hours per response	Total hours
Exemptions—803.19		57	4	228	3	684
User Facility Reporting—803.30 and 803.32		544	9	4,896	1	4,896
User Facility Annual Reporting—803.33	FDA Form 3419	195	1	195	1	195
Importer Reporting, Death and Serious Injury—803.40 and 803.42		1	1	1	1	1
Manufacturer Reporting—803.50, through 803.53		1,239	243	301,077	1	301,077
Supplemental Reports—803.56		124	302	37,448	1	37,448
Total						344,301

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
MDR Procedures—803.17	220	1	220	10	2,200
MDR Files—803.18	30,000	1	30,000	1.5	45,000
Total					47,200

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

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	1	25	25	1	25

Dated: June 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13832 Filed 6–6–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0178]

International Conference on Harmonisation; Guidance on S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use'' (ICH S2(R1)). This guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The ICH S2(R1) combines and replaces two ICH guidances, ''S2A Specific Aspects for Regulatory Genotoxicity Tests for Pharmaceuticals'' and ''S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals.'' ICH S2(R1) provides guidance to drug sponsors on which tests should be performed to assess potential genotoxicity of pharmaceuticals. It also provides guidance on testing conditions, data interpretation, and followup strategies if a positive response is seen in in vitro assays. This guidance is intended to provide drug sponsors with recommendations to ensure that drugs are appropriately tested for potential to cause genetic damage and to ensure efficient development of new drugs.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the 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, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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:

Regarding the Guidance

David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6488,