Emergency Shortages Data Collection System (formerly ''Emergency Medical Device Shortages Program Survey'')—Section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0491)—Extension

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)), the FDA Commissioner is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. Subsequent to the events of September 11, 2001, and as part of broader counter-terrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable CDRH to anticipate and respond to medical device shortages that might arise in the context of federally-declared disasters/emergencies or regulatory actions. In particular, CDRH identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans and raw material constraints for medical devices that would be in high demand, and/or would be vulnerable to shortages in specific disaster/emergency situations, or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, and support real-time decisionmaking by the Department of Health and Human Services during actual emergencies or emergency preparedness exercises.

''The Emergency Medical Device Shortages Program Survey'' was developed in 2002 to support the acquisition of such data from medical device manufacturers. In 2004, CDRH changed the process for the data collection, and the electronic database in which the data were stored and was formally renamed the ''Emergency Shortages Data Collection System'' (ESDCS). Recognizing that some of the data collected may be commercially confidential, access to ESDCS is restricted to members of the FDA Emergency Shortage Team (EST) and senior management with a need-to-know. At this time, the need-to-know senior management personnel are limited to 5 senior managers. Further, the data are used by this defined group only for decisionmaking and planning in the context of a federally-declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by non-disaster-related device shortage.

The data procurement process consists of an initial scripted telephone call to a regulatory officer at a registered manufacturer of one or more key medical devices being tracked in the emergency shortages data collection system. In this initial call, the intent and goals of the data collection effort are described, and the specific data request is made. After the initial call, one or more additional followup calls and/or electronic mail correspondence may be required to verify/validate data sent from the manufacturer, confirm receipt and/or request additional detail. Although the regulatory officer is the agent who is initially contacted, they may designate an alternate representative within their organization to correspond subsequently with the CDRH EST member who is collecting or verifying/validating the data.

Because of the dynamic nature of the medical device industry, particularly with respect to specific product lines, manufacturing capabilities and raw material/subcomponent sourcing, it is necessary to update the data in the ESDCS at regular intervals. This is done on a weekly basis, but efforts are made to limit the frequency of outreach to a specific manufacturer to no more than every 4 months.

The ESDCS will only include those medical devices for which there will likely be high demand during a specific emergency/disaster, or for which there are sufficiently small numbers of manufacturers such that disruption of manufacture or loss of one or more of these manufacturers would create a shortage.

In the **Federal Register** of December 19, 2008 (73 FR 77718), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
903(d)(2)	125	3	375	0.5	188

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

FDA based the burden estimates in Table 1 of this document on past experience with direct contact with the medical device manufacturers, and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year to either obtain primary data or to verify/validate data. Because the data being requested represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Dated: May 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10816 Filed 5–7–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Title IV–E Foster Care Eligibility Review and Child and Family Service Reviews; Final Rule.

OMB No.: 0970–0214.

Description: The following five separate activities are associated with this information collection: Foster Care Eligibility Review (FCER) Program Improvement Plan; Child and Family Services Reviews (CFSR) State agency

Statewide Assessment; CFSR On-site Review; CFSR Program Improvement Plan; and Anti-Discrimination Enforcement Corrective Action Plan. The collection of information for review of Federal payments to States for foster care maintenance payments (45 CFR 1356.71(i)) is authorized by title IV–E of the Social Security Act (the Act), section 474 [42 U.S.C. 674]. The Foster Care Eligibility Reviews (FCER) ensure that States claim title IV–E funds only on behalf of title IV–E eligible children. The collection of information for review of State child and family services programs (45 CFR 1355.33(b), 1355.33(c) and 1355.35(a)) is to determine whether such programs are in substantial conformity with State plan requirements under parts B and E of the Act and is authorized by section 1123(a) [42 U.S.C 1320a–1a] of the Act. The CFSR looks at the outcomes related to safety, permanency and well-being of children served by the child welfare system and at seven systemic factors that support the outcomes. Section 474(d) of the Act [42 U.S.C 674] deploys enforcement provisions (45 CFR 1355.38(b) and (c)) for the requirements at section 4371(a)(18) [42 U.S.C 671], which prohibit the delay or denial of foster and adoptive placements based on the race, color, or national origin of any of the individuals involved. The enforcement provisions include the execution and completion of corrective action plans when a State is in violation of section 471(a)(18) of the Act. The information collection is needed: (1) To ensure compliance with title IV–E foster care eligibility requirements; (2) to monitor State plan requirements under titles IV–B and IV–E of the Act, as required by Federal statute; and (3) to enforce the title IV–E anti-discrimination requirements through State corrective action plans. The resultant information will allow ACF to determine if States are in compliance with State plan requirements and are achieving desired outcomes for children and families, help ensure that claims by States for title IV–E funds are made only on behalf of title IV–E eligible children, and require States to revise applicable statutes, rules, policies and procedures, and provide proper training to staff, through the development and implementation of corrective action plans. These reviews not only address compliance with eligibility requirements but also assist States in enhancing the capacities to serve children and families. In computing the number of burden hours for this information collection, ACF based the annual burden estimates on ACF's and States' experiences in conducting reviews and developing program improvement plans.

Respondents: State Title IV–B and Title IV–E Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 1356.7 (i) Program Improvement Plan (FCER)	7	1	90	630
45 CFR 1366.33 (b) Statewide Assessment (CFSR)	13	1	240	3,120
45 CFR 1355.33 (c) On-site Review (CFSR)	13	1	1,170	15,210
45 CFR 1355.35 (a) Program Improvement Plan (CFSR)	13	1	240	3,120
45 CFR 1355.38 (b) and (c) Corrective Action	1	1	780	780

Estimated Total Annual Burden Hours: 22,860

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail 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.

Dated: May 5, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–10703 Filed 5–7–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Regulations

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 June 8, 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 0910–0014. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.