

431,148. (For policy questions regarding this collection contact: Christine Dobrzycki at 410-786-3389. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on March 27, 2009.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: February 12, 2009.

Michelle Shortt,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care Quarterly Case Record Report—ACF-801.

OMB No.: 0970-0167.

Description: Section 658K of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101-508, 42 U.S.C. 9858) requires that States and Territories submit monthly case-level data on the children and families receiving direct services under the Child Care and Development Fund. The

implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Case level reports, submitted quarterly or monthly (at grantee option), include monthly sample or full population case level data. The data elements to be included in these reports are represented in the ACF-801. ACF uses disaggregate data to determine program and participant characteristics as well as costs and levels of child care services provided. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and regulations, ACF requests extension of the ACF-801. With this extension, ACF is proposing several changes and clarifications to the reporting requirements and instructions.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Mariana Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-801	56	4	20	4,480

Estimated Total Annual Burden Hours: 4,480

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: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: February 17, 2009.

Janean Chambers,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0075]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register**

concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on medical device reporting (MDR); manufacturer, importer, user facility, and distributor reporting.

DATES: Submit written or electronic comments on the collection of information by April 27, 2009.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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.