

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, Bethesda, MD 20892, 301-451-8754, tuo@nei.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 10, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-05824 Filed 3-13-15; 8:45 am]

BILLING CODE 4140-01-P

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 (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 (CCDF). 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. On November 19, 2014, the President signed the Child Care and Development Block Grant Act of 2014 (Pub. L. 113-86) which reauthorized the CCDF program and made some changes to ACF-801 reporting requirements. Owing to the need to consult with CCDF administrators and other interested parties on these changes, and a limited amount of time before the current ACF-801 form expires, ACF is not proposing changes to the ACF-801 at this time. We request to extend the ACF-801 without changes in order to ensure the form does not expire. In the near future, ACF plans to initiate a new clearance process under the Paperwork Reduction Act to implement the data reporting changes in the newly-reauthorized law.

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	25	5,600
Estimated total annual burden hour	5,600

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email 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, *Email: OIRA_SUBMISSION@OMB.EOP.GOV*, Attn:

Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015-05918 Filed 3-13-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0793]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority

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 the information collection requirements for medical device recall authority.

DATES: Submit either electronic or written comments on the collection of information by May 15, 2015.

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: 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: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical

utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Recall Authority—21 CFR 810 (OMB Control Number 0910-0432)—Extension

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and part 810 (21 CFR part 810), medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death, to: (1) Immediately cease distribution of such device; (2) immediately notify health professionals and device-user facilities of the order; and (3) instruct such professionals and facilities to cease use of such device.

Further, the provisions under section 518(e) of the FD&C Act set out the

following three-step procedure for issuance of a mandatory device recall order:

- If there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately:
 - Cease distribution of the device,
 - notify health professionals and device user facilities of the order, and
 - instruct those professionals and facilities to cease use of the device;
- FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device; and
- after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the Agency determines that such an order is necessary.

The information collected under the recall authority provisions will be used by FDA to do the following: (1) Ensure that all devices entering the market are safe and effective; (2) accurately and immediately detect serious problems with medical devices; and (3) remove dangerous and defective devices from the market.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Collection activity—21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Collections Specified in the Order—810.10(d)	2	1	2	8	16
Request for Regulatory Hearing—810.11(a)	1	1	1	8	8
Written Request for Review—810.12(a-b)	1	1	1	8	8
Mandatory Recall Strategy—810.14	2	1	2	16	32
Periodic Status Reports—810.16(a-b)	2	12	24	40	960
Termination Request—810.17(a)	2	1	2	8	16
Total hours					1,040

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Collection activity—21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Documentation of Notifications to Recipients—810.15(b) ...	2	1	1	8	8

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

Collection activity—21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification to Recipients—810.15(a)–(c)	2	1	2	12	24
Notification to Recipients; Followup—810.15(d)	2	1	2	4	8
Notification of Consignees by Recipients—810.15(e)	10	1	10	1	10
Total					42

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

Dated: March 10, 2015.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2015–05868 Filed 3–13–15; 8:45 am]
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DEPARTMENT OF HOMELAND SECURITY
Federal Emergency Management Agency
[Docket ID FEMA–2015–0001]
Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.
ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency’s

(FEMA’s) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of January 7, 2015 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at www.msc.fema.gov by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) Luis.Rodriguez3@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations

listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at www.msc.fema.gov.

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below. (Catalog of Federal Domestic Assistance No. 97.022, “Flood Insurance.”)

Dated: February 23, 2015.
Roy E. Wright,
Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Floyd County, Iowa and Incorporated Areas Docket No.: FEMA–B–1342	
City of Charles City	City Hall, 105 Milwaukee Mall, Charles City, IA 50616.
Unincorporated Areas of Floyd County	Floyd County Courthouse, 101 South Main Street, Suite 108, Charles City, IA 50616.