Estimated Total Annual Burden Hours: 51,845.88

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: November 8, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–28447 Filed 11–10–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Community-Based Family Resource and Support Grants (Name changed to Child Abuse Prevention Program—OIS notified 6/2007).

OMB No.: 0970–0155.

Description: The Program Instruction, prepared in response to the enactment of the Community-Based Grants for the Prevention of Child Abuse and Neglect (administratively known as the Community Based Child Abuse Prevention Program, (CBCAP), as set forth in Title II of Public Law 108–36, Child Abuse Prevention and Treatment Act Amendments of 2003, and in the process of reauthorization, provides direction to the States and Territories to accomplish the purposes of (1) supporting community-based efforts to develop, operate, expand, and where appropriate to network, initiatives aimed at the prevention of child abuse and neglect, and to support networks of coordinated resources and activities to better strengthen and support families to reduce the likelihood of child abuse and neglect, and; (2) fostering an understanding, appreciation, and knowledge of diverse populations in order to be effective in preventing and treating child abuse and neglect. This Program Instruction contains information collection requirements that are found in (Pub. L. 108–36) at sections 201; 202; 203; 205; 206; 207; and pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute, complete the calculation of the grant award entitlement, and provide training and technical assistance to the grantee.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application	52	1	40	2,080
Annual Report	52	1	24	1,248

Estimated Total Annual Burden Hours: 3,328.

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: November 8, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–28445 Filed 11–10–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0555]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking

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 information collection requirements for the tracking of medical devices.

DATES: Submit either electronic or written comments on the collection of information by January 11, 2011.

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: 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: 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.

In preparing this notice, the agency reviewed a comment that was posted in response to the 60-day notice of February 5, 2008 (73 FR 6729) (Docket No. FDA–2008–N–0050). FDA transitioned to the Federal Dockets Management System (FDMS) in January 2008, and this comment was not posted to the docket until after the closing of the comment period. The comment responded to item 1 (whether the information collection is necessary) and item 3 (how to enhance quality of ICR). With regard to item 1, the comment emphasized the importance of medical device tracking and supported the information collection request in full. With regard to item 3, the comment said that implementing the unique device identification provision (UDI) of the Food and Drug Administration Modernization Act (FDAMA) would go a long way in enhancing medical device tracking, and the agency is currently undertaking this effort.

Medical Devices; Device Tracking—21 CFR Part 821 (OMB Control Number 0910–0442)—Extension

Section 211 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115) became effective on February 19, 1998. FDAMA amended the previous medical device tracking provisions under section 519(e)(1) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(e)(1) and (e)(2)) and were added by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629). Unlike the tracking provisions under SMDA which required tracking of any medical device meeting certain criteria, FDAMA allows FDA discretion in applying tracking provisions to medical devices meeting certain criteria, and provides that tracking requirements for medical devices can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule which conformed existing tracking regulations to changes in tracking provisions effected by FDAMA under part 821 (21 CFR part 821).

Section 519(e)(1) of the act, as amended by FDAMA, provides that FDA may require by order, that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a "tracked implant"), or (3) the device is life-sustaining or life-supporting (referred to as a "tracked l/s-l/s device") and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary), use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, e.g., distributors; records and inspection requirements; (4) confidentiality; and (5) record retention requirements.

Respondents for this collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
821.1(d)	1	1	1	1	1
821.2 and 821.30(e)	1	1	1	1	1
821.25(a)	12	1	12	76	912

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
821.25(d)	1	1	1	1	1
Total					915

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

CFR section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
821.25(b)	12	46,260	555,120	1	555,120
821.25(c)[2]	12	1	12	63	756
821.25(c)(3)	12	1,124	13,488	1	13,488
Total					569,364

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

21 CFR section	Number of respondents	Annual frequency of disclosure	Total annual disclosures	Hours per disclosure	Total hours
821.30(a) and (b)	17,000	1	17,000	1	17,000
821.30(c) and (d)	17,000	1	17,000	1	17,000
Total Hours					34,000

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

The annual hourly burden for respondents involved with medical device tracking is estimated to be 604,279 hours per year. The burden estimates cited in tables 1, 2, and 3 of this document are based on the number of device tracking orders issued in the last 3 years.

This regulation also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information found in 21 CFR 821.2(b), 821.25(e), and 821.30(e) have been approved under OMB control number 0910–0183.

Dated: November 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28441 Filed 11–10–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0319]

Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "Dear Health Care Provider Letters: Improving Communication of Important Safety Information." Dear Health Care Provider (DHCP) Letters are correspondence—usually in the form of a mass mailing from the manufacturer or distributor of a human drug or biologic, or from FDA—intended to alert physicians and other health care providers to important new information about a marketed drug or biological product. This draft guidance provides recommendations on when to use a DHCP letter, the types of information to include in a DHCP letter, how to organize that information, and formatting techniques to make the information more accessible. The draft guidance is intended to improve the quality of DHCP letters to make them more effective communication tools for new information about marketed products.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 11, 2011.

ADDRESSES: Submit written requests for single copies of the draft 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