Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2013–26632 Filed 11–6–13; 8:45 am]

BILLING CODE 4163–18–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).

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 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 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. 2013–26672 Filed 11–6–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0575]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics

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 December 9, 2013.

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—New and title ''Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics.'' Also include the FDA 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics—(OMB Control Number 0910–New)

Description of Respondents: Respondents to this collection of

information are sponsors that develop drugs and biological products.

Burden Estimate: This guidance outlines FDA's policies and procedures related to the following expedited programs for serious conditions: (1) Fast track designation including rolling review, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. In addition, this guidance describes threshold criteria generally applicable to these expedited programs.

This guidance refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 202.1, 314, and 601, and sections 505(a), 506(a)(1), 735, and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a), 356(a)(1), 379(g), and 379(h)) have been approved under OMB control numbers 0910–0686, 0910–0001, 0910–0338, 0910–0014, and 0910–0297.

This guidance proposes the following new collections of information:

Priority Review Designation Request. The guidance describes that a sponsor may expressly request priority review of an application. Based on information from FDA's databases and information available to FDA, we estimate that approximately 47 sponsors will prepare and submit approximately 1 priority review designation submission in accordance with the guidance and that the added burden for each submission will be approximately 30 hours to develop and submit to FDA as part of the application (totaling 1,410 hours).

Breakthrough Therapy Designation Request. The guidance describes the process for sponsors to request breakthrough therapy designation in an application. Based on information available to FDA, we estimate that approximately 24 sponsors will prepare approximately 1 breakthrough therapy designation submission in accordance with the guidance and that the added burden for each submission will be approximately 70 hours to prepare and submit (totaling 1,680 hours).

Promotional Materials for Accelerated Approval Under Part 314. The guidance describes section 506(b)(2)(B) of the FD&C Act and FDA's accelerated approval regulations (§§ 314.550 and 601.45). These provisions authorize FDA to require sponsors to submit copies of all promotional materials to the Agency for consideration prior to their dissemination. The regulations provide that copies of all promotional materials including promotional labeling as well as advertisements intended for dissemination or publication within 120 days following marketing approval must be submitted to FDA during the preapproval period. The regulations further provide that after 120 days following marketing approval, unless otherwise informed by the Agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. Currently, FDA has OMB approval for the submission of copies of all promotional materials under part 601 (OMB control number 0910–0338) but does not have approval for the submission of copies of all promotional materials under part 314.

Based on information from FDA's databases and information available to FDA, we estimate that approximately 20 sponsors will submit promotional materials for accelerated approval 7 times annually in accordance with § 314.550 and that the burden for each submission will be approximately 120 hours (a total of 16,800 hours).

In the **Federal Register** of June 26, 2013 (78 FR 38349), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 26 comments. However, these comments did not address the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance on expedited programs	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Designation Request	47	1	47	30	1,410
Breakthrough Therapy Designation Request	24	1	24	70	1,680
Promotional Materials for Accelerated Approval Under § 314.550	20	7	140	120	16,800
Total hours					19,890

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

Dated: November 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26695 Filed 11–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1295]

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.'' This draft guidance clarifies the distinction between hearing aids and personal sound amplification products (PSAPs), as well as the regulatory controls that apply to each. This draft guidance is not final nor is it in effect at this time.

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 February 5, 2014.