classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2013.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: The agenda for the Advisory Board meeting includes: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; Update on 10-Year Review Implementation; SEC petitions for: Hanford (1987–1989; petition #155), Battelle Laboratories—King Avenue (Columbus, OH), Savannah River Site, General Steel Industries (Granite City, IL), Baker Brothers (Toledo, OH), and Joslyn Manufacturing and Supply Co. (Fort Wayne, IN); SEC Petitions Status Update; and Board Work Sessions.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted in accordance with the redaction policy provided below. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Policy on Redaction of Board Meeting Transcripts (Public Comment): (1) If a person making a comment gives his or her name, no attempt will be made to redact that name. (2) NIOSH will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include: (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH Web site; (d) A statement such as in (a) above will appear in the **Federal Register** Notice that announces Board and Subcommittee meetings. (3) If an individual in making a statement reveals personal information (e.g., medical information) about themselves that information will not usually be redacted. The NIOSH FOIA coordinator will, however, review such revelations in accordance with the Freedom of Information Act and the Federal Advisory Committee Act and if deemed appropriate, will redact such information. (4) All disclosures of information concerning third parties will be redacted. (5) If it comes to the attention of the DFO that an individual wishes to share information with the Board but objects to doing so in a public forum, the DFO will work with that individual, in accordance with the Federal Advisory Committee Act, to find a way that the Board can hear such comments.

Contact Person for More Information: Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, MS E–20, Atlanta GA 30333, telephone: (513) 533–6800, toll free: 1–800–CDC–INFO, email: *dcas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 9, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–28023 Filed 11–16–12; 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: Child Care and Development Fund Annual Financial Report (ACF–696T) for Tribes.

OMB No.: 0970–0195.

Description: Tribes use the Financial Report Form ACF–696T to report Child Care and Development Fund (CCDF) expenditures. Authority to collect and report this information is found in Section 658G of the Child Care and Development Block Grant Act of 1990, as revised. In addition to the Program Reporting Requirements set forth in 45 CFR Part 98, Subpart H, the regulations at 45 CFR 98.65(g) and 98.67(c)(1) authorize the Secretary to require financial reports as necessary.

Tribal grantees submit the ACF–696T report on an annual basis on behalf of the Tribal Lead Agency administering the Child Care and Development Fund (CCDF).

The collection will not duplicate other information.

Respondents: Tribes and Tribal Organizations that are CCDF grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–696T CCDF Financial Reporting Form for Tribes	272	1	6	1,632

Estimated Total Annual Burden Hours: 1,632.

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. 2012–28061 Filed 11–16–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1045]

Medical Devices; Custom Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration Safety and Innovation Act (FDASIA), which was signed into law on July 9, 2012, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The Food and Drug Administration (FDA) is in the process of developing an implementation strategy and policy for the custom device exemption criteria in the FD&C Act amended by FDASIA. FDA is seeking information on appropriate uses of the custom device exemption.

DATES: Submit either electronic or written comments by January 18, 2013.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852.

FOR FURTHER INFORMATION CONTACT: Bryan Benesch, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3424, Silver Spring, MD 20993–0002, 301–796–5506.

SUPPLEMENTARY INFORMATION:

I. Background

Section 520(b) of the FD&C Act (21 U.S.C. 360j(b), as amended by section 617 of FDASIA (Pub. L. 112–144), sets forth the requirements that must be met in order for a device to qualify for a custom device exemption (Ref. 1). Section 520(b) of the FD&C Act exempts ''custom devices'' from performance standard or premarket approval requirements under sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e), if these devices meet the enumerated statutory requirements, including, among others, the following for each device: (1) Is ''created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing)''; (2) must not be ''generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution''; (3) must be for the purpose of treating a ''unique pathology or physiological condition that no other device is domestically available to treat''; and (4) must be manufactured for the ''special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of the physician or dentist (or other specially qualified person so designated)'' or by an individual patient named in such order.

In addition to these new requirements for establishing a custom device, manufacturers will have limitations for use of a custom device only for the purpose of treating a ''sufficiently rare condition, such that conducting clinical investigations on such device would be impracticable'' and production of the device must be limited to no more than five units per year of a particular device type. Lastly, manufacturers will be required to submit an annual report explaining their use of the custom device exemption under section 617 of FDASIA.

FDA is seeking information on and examples of appropriate uses of the custom device exemption identified in section 520(b) of the FD&C Act. FDA encourages all stakeholders, including patients, physicians, dentists, and manufacturers, to submit comments on the appropriate use of this statutory provision.

FDA is particularly interested in receiving information relating to:

1. Input from patients, manufacturers, dentists, or physicians on where use of the custom device exemption is appropriate.

2. Specific instances where manufacturers, dentists, or physicians have used, would have liked to use, or plan to use the custom device exemption for treatment of a sufficiently rare condition.

3. Product areas other than orthopedic and dental devices where the custom device exemption may be useful.

4. The type of information manufacturers intend to require a physician, dentist, or other qualified person to submit to them when ordering a custom device.

5. How often a custom device is ordered due to unusual anatomical features of the individual physician/dentist, or due to a unique need in the physician's/dentist's practice not shared by health professionals of the same specialty (i.e., a special need of a physician or dentist).

This notice provides the first opportunity for the public to comment on these issues. The public will have a second opportunity to provide input when the Agency announces the availability of a draft guidance document and a draft regulation for implementing section 520(b) of the FD&C Act.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov*.

1. The Food and Drug Administration Safety and Innovation Act, available at *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm20027187.htm*.

Dated: November 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28042 Filed 11–16–12; 8:45 am]

BILLING CODE 4160–01–P