

performed for purposes of the compensation program, and advice on petitions to add 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; SEC petitions for: Rocky Flats Plant, Sandia National Laboratory—Livermore (Livermore, CA); Site Profile reviews for: General Steel Industries, DuPont Deepwater Works (Deepwater, New Jersey); Procedures Review Subcommittee Report; SEC Issues Work Group Report on “Sufficient Accuracy”/ Co-Worker Dose Modeling; SEC Petitions 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 personal information, no attempt will be made to redact the name; however, NIOSH will redact other personally identifiable information, such as contact information, social security numbers, case numbers, etc., of the commenter.

(2) If an individual in making a statement reveals personal information (e.g., medical or employment information) about themselves that information will not usually be redacted. The NIOSH Freedom of Information Act (FOIA) coordinator will, however, review such revelations in accordance with the Federal Advisory Committee Act and if deemed appropriate, will redact such information.

(3) If a commenter reveals personal information concerning a living third party, that information will be reviewed by the NIOSH FOIA coordinator, and upon determination, if deemed appropriated, such information will be redacted, unless the disclosure is made by the third party’s authorized representative under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program.

(4) In general, information concerning a deceased third party may be disclosed; however, such information will be redacted if (a) the disclosure is made by an individual other than the survivor claimant, a parent, spouse, or child, or the authorized representative of the deceased third party; (b) if it is unclear whether the third party is living or deceased; or (c) the information is unrelated or irrelevant to the purpose of the disclosure.

The Board 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.

Contact Person For More Information: Theodore Katz, Designated Federal Official, 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 CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency

Review by the Office of Management and Budget (OMB)

Title: OCSE-75 Tribal Child Support Enforcement Program Annual Data Report.

OMB No.: 0970-0320 New Collection.

Description: The data collected by form OCSE-75 are used to prepare the OCSE preliminary and annual data reports. In addition, Tribes administering CSE programs under Title IV-D of the Social Security Act are required to report program status and accomplishments in an annual narrative report and submit the OCSE-75 report annually.

Respondents: Tribal Child Support Enforcement Organizations or the Department/Agency/Bureau responsible for Child Support Enforcement in each tribe.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-75	60	1	60	3,600

Estimated Total Annual Burden
Hours: 3,600

Additional Information:

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by September 30, 2013. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690-7275.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503; FAX: (202) 395-7285; email:

oir_submission@omb.eop.gov.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0636]

Global Unique Device Identification Database; Draft Guidance for Industry; 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 “Global Unique Device Identification Database (GUDID).” FDA is issuing this draft guidance to communicate our current thinking of how the GUDID will operate. The guidance includes both information about how device labelers (in most instances, the device manufacturer) will interface with the GUDID, as well as information on the database elements that must be submitted to the GUDID and their definitions. We intend to publish a final guidance after the close of the comment period and our implementation of the GUDID.

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 November 25, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Global Unique Device Identification Database (GUDID)” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send a fax request to 301-847-8149 to receive a hard copy. Alternatively, you may submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jay Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3216, Silver Spring, MD 20993-0002, email: udi@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007, 121 Stat. 854, and Section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, 126 Stat. 1061, amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The unique device identification (UDI) system proposed rule was published on

July 10, 2012 (77 FR 40736), followed by an amendment modifying the implementation timeframe for certain devices, which was published on November 19, 2012 (77 FR 69393).

In developing the proposed rule, FDA solicited and considered input from a variety of stakeholders (e.g., manufacturers, global regulatory bodies, the clinical community, patient advocates) to ensure that as many perspectives as possible were incorporated. The GUDID is a critical component of the UDI System. While the UDI assigned to each device is a globally unique, yet unintelligent code, the GUDID will house a uniform set of required attribute information, including the device identifier (DI) component of the UDI, for the devices reported to the GUDID. Being unique for each device, the DI component of the UDI can be effectively used by stakeholders to access the other GUDID attribute information for that device.

Labelers will be responsible for submitting information to the GUDID as part of their UDI requirements. This draft guidance document describes how labelers would obtain access to the GUDID, how to submit DI records to the GUDID, and how all stakeholders can search and retrieve device information. This draft guidance is being issued to provide general information about the GUDID.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on the GUDID. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or at <http://www.regulations.gov>. To receive “Global Unique Device Identification Database (GUDID),” you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send