

under review (sets 7–10); OCAS dose reconstruction quality management and assurance activities.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. 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.

**Contact Person for more Information:** Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta, Georgia 30333, Telephone (513) 533-6800, Toll Free 1(800) CDC-INFO, e-mail [ocas@cdc.gov](mailto:ocas@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: June 23, 2011.

**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

### Centers for Disease Control and Prevention

#### Subcommittee on Procedures Review, Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned subcommittee:

**TIME AND DATE:** 9 a.m.–5 p.m., July 14, 2011.

**PLACE:** Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018, Telephone (859)334-4611, Fax (859)334-4619.

**STATUS:** Open to the public, but without a public comment period. To access by conference call dial the following information: (866)659-0537, Participant Pass Code 9933701.

**Background:** The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of

the ABRWH include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being 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 ABRWH to HHS, which subsequently delegated this authority to 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, 2011.

**PURPOSE:** The ABRWH 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, advising 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 a reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee on Procedures Review was established to aid the ABRWH in carrying out its duty to advise the Secretary, HHS, on dose reconstructions. The Subcommittee on Procedures Review is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor.

**MATTERS TO BE DISCUSSED:** The agenda for the Subcommittee meeting includes discussion of the Norton Company Special Exposure Cohort Petition (1962–2009) and discussion of the following ORAU and OCAS procedures: ORAUT-RPRT-0044 (“Analysis of Bioassay Data with a Significant Fraction of Less-Than Results”), OCAS TIB-0013 (“Special External Dose Reconstruction Considerations for Mallinckrodt Workers”), OTIB-019 (“Analysis of Coworker Bioassay Data for Internal Dose Assignment”), OTIB-0029 (“Internal Dosimetry Coworker Data for

Y-12”), OTIB-0047 (“External Radiation Monitoring at the Y-12 Facility During the 1948–1949 Period”), OTIB-0049 (“Estimating Doses for Plutonium Strongly Retained in the Lung”), OTIB-0052 (“Parameters to Consider When Processing Claims for Construction Trade Workers”), OTIB-0054 (“Fission and Activation Product Assignment for Internal Dose-Related Gross Beta and Gross Gamma Analyses”), and OTIB-0070 (“Dose Reconstruction During Residual Radioactivity Periods at Atomic Weapons Employer Facilities”); and a continuation of the comment-resolution process for other dose reconstruction procedures under review by the Subcommittee.

The agenda is subject to change as priorities dictate.

This meeting is open to the public, but without a public comment period. In the event an individual wishes to provide comments, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below in advance of the meeting.

#### **CONTACT PERSON FOR MORE INFORMATION:**

Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta, Georgia 30333, Telephone (513)533-6800, Toll Free 1(800) CDC-INFO, E-mail [dcas@cdc.gov](mailto:dcas@cdc.gov).

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Dated: June 23, 2011.

**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:** Evaluation of Adolescent Pregnancy Prevention Approaches: Baseline Data Collection.

OMB No.: 0970-0360.

**Description:** The Office of Adolescent Health (OAH), Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), is overseeing and coordinating adolescent pregnancy prevention evaluation efforts as part of the Teen Pregnancy Prevention Initiative. OAH is working collaboratively with the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Centers for Disease Control and Prevention (CDC), and the Administration for Children and Families (ACF) on adolescent pregnancy prevention evaluation activities.

The Evaluation of Adolescent Pregnancy Prevention Approaches (PPA) is one of these efforts. PPA is a random assignment evaluation which will expand available evidence on

effective ways to reduce teen pregnancy. The evaluation will document and test a range of pregnancy prevention approaches in up to eight program sites. The findings from the evaluation will be of interest to the general public, to policy-makers, and to organizations interested in teen pregnancy prevention.

OAH and ACF are proposing baseline data collection activity as part of the PPA evaluation. Baseline data collection instruments were already approved on July 26, 2010. The project has worked in recent months to secure grantees as evaluation sites, and as part of this effort the project has undertaken making revisions to the baseline instrument with each site. These revisions were undertaken because each site has unique features (e.g. target population; curriculum; objectives) and the baseline instruments were tailored to take these

features into account. OAH and ACF are now requesting emergency clearance to collect data using site-specific instruments.

Respondents will be asked to answer carefully selected questions about demographics and risk and protective factors related to teen pregnancy. Information from this data collection will be used to perform meaningful analysis to determine significant program effects.

**Respondents:** The survey data will be collected through private, self-administered questionnaires completed by study participants, i.e. adolescents assigned to a select school or community teen pregnancy prevention program or a control group. Surveys will be distributed and collected by trained professional staff.

#### ANNUAL BURDEN ESTIMATES

Site/program (and name of baseline instrument)	Annualized no. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours (annual)
Children's Hospital of Los Angeles/Project AIM .....	467	1	.7	327
Oklahoma Institute of Child Advocacy/Power Through Choices .....	360	1	.6	216
Engender Health/Gender Matters .....	375	1	.6	225
Ohio Health/T.O.P.P. ....	200	1	.7	140
Live the Life Ministries/WAIT Training .....	533	1	.7	373
Princeton Center for Leadership Training (PCLT)/TeenPEP .....	533	1	.6	320
<b>Total</b> .....	<b>2468</b>	.....	.....	<b>1601</b>

*Estimated Total Annual Burden Hours: 1601.*

#### Additional Information:

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by July 1, 2011. A copy of this information collection, with applicable supporting documentation, may be obtained by e-mailing [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

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) 395-6974.

**Robert Sargis,**

*Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2011-N-0439]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Recall Regulations

**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 reporting requirements on FDA recalls.

**DATES:** Submit either electronic or written comments on the collection of information by August 29, 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](mailto: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