

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, GA 30333, Telephone (513) 533-6800, Toll Free 1 (800) CDC-INFO, E-mail [dcas@cdc.gov](mailto: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: February 24, 2011.

**Elaine L. Baker,**

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

[FR Doc. 2011-4597 Filed 3-1-11; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-9978-N2]

#### Public Meeting of the Consumer Operated and Oriented Plan (CO-OP) Advisory Board, March 14, 2011

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces the third meeting of an advisory committee to the Center for Consumer Information and Insurance Oversight (CCIIO) in accordance with the Federal Advisory Committee Act. The meeting is open to the public. The purpose of the meeting is to assist and advise the Secretary and the Congress on the Department's strategy to foster the creation of qualified nonprofit health insurance issuers. Specifically, the Committee

shall advise the Secretary and the Congress concerning the award of grants and loans related to Section 1322 of the Affordable Care Act, which provides for a Federal program to assist establishment and operation of nonprofit, member run health insurance issuers. In these matters, the Committee shall consult with all components of the Department, other federal entities, and non-Federal organizations, as appropriate; and examine relevant data sources to assess the grant and loan award strategy to provide recommendations to CCIIO.

**DATES:** *Meeting Date:* March 14, 2011 from 8:30 a.m. to 5 p.m., Eastern Standard Time (EST) *Deadline for Meeting Registration, Presentations and Comments:* March 10, 2011, 5 p.m., EST. *Deadline for Requesting Special Accommodations:* March 10, 2011, 5 p.m., EST.

**ADDRESSES:** *Meeting Location:* Madison Hotel, 1177 15th Street, NW., Washington, DC 20005.

*Meeting Online Access:* To participate in this meeting via the Internet, go to <http://www.readyshow.com/> and enter participant code 49888151. Note that audio of the meeting will only be broadcast through the conference phone line.

*Meeting Phone Access:* To participate in this meeting via phone, please dial into the toll free phone number 1-888-299-4099, and provide the following code to the operator: VW38426.

*Meeting Registration, Presentations, and Written Comments:* Anne Bollinger, Center for Consumer Information and Insurance Oversight, CMS, 200 Independence Avenue, SW., Washington, DC 20201, 301-492-395, Fax: 301-492-4462, or contact by e-mail at [anne.bollinger@hhs.gov](mailto:anne.bollinger@hhs.gov). Written comments must be submitted in Word format.

*Registration:* The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the designated Federal official at the address listed in the **ADDRESSES** section of this notice or by telephone at the number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by the date listed in the **DATES** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Anne Bollinger, 301-492-4395. Press inquiries are handled through CCIIO's Press Office at (202) 690-6343.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The purpose of the meeting is to assist and advise the Secretary and the

Congress on the Department's strategy to foster the creation of qualified nonprofit health insurance issuers. Specifically, the Committee shall advise the Secretary and the Congress concerning the award of grants and loans related to section 1322 of the Affordable Care Act, which provides for a Federal program to assist establishment and operation of nonprofit, member run health insurance issuers. In these matters, the Committee shall consult with all components of the Department, other Federal entities, and non-Federal organizations, as appropriate; and examine relevant data sources to assess the grant and loan award strategy to provide recommendations to CCIIO.

##### **II. Meeting Agenda**

The Committee will hear comments from the public and then begin deliberations on proposed recommendations presented by the work groups from the Committee. CCIIO intends to make background material available to the public no later than two (2) business days prior to the meeting. If CCIIO is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on CCIIO's Web site after the meeting, at <http://hhs.gov/CCIIO>.

Oral comments from the public will be scheduled between approximately 8:30 a.m.-9:30 a.m. Individuals or organizations that wish to make a 3-minute oral presentation on an agenda topic should submit a written copy in Word format of the oral presentation to the designated federal official (DFO) at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Persons attending CCIIO's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public comment session, CCIIO will take written comments after the meeting until close of business. Individuals not wishing to make a presentation may submit written comments in Word format to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Individuals requiring sign language interpretation or other special accommodations must contact the DFO via the contact information specified in

the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

CCIO is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.hhs.gov/CCIO> for procedures on public conduct during advisory committee meetings.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 24, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2011-4556 Filed 2-25-11; 11:15 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0542]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information Request Regarding Dissolvable Tobacco Products

**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 (the PRA).

**DATES:** Fax written comments on the collection of information by April 1, 2011.

**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 e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-NEW and title “Information Request Regarding Dissolvable Tobacco Products.” Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management, Food and Drug

Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794,

[Jonnalynn.Capezzuto@fda.hhs.gov](mailto:Jonnalynn.Capezzuto@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.

#### Information Request Regarding Dissolvable Tobacco Products—(OMB Control Number 0910-NEW)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 917 of the Tobacco Control Act (21 U.S.C. 387g) requires the Secretary of Health and Human Services (the Secretary) to establish a Tobacco Products Scientific Advisory Committee (TPSAC). Section 907(f) of the Tobacco Control Act (21 U.S.C. 387g(f)) requires the TPSAC to submit a report and recommendations to the Secretary on the impact of the use of dissolvable tobacco products on the public health, including such use among children. To ensure a comprehensive review of this issue, FDA is requesting tobacco industry documents and information to support the work of TPSAC. Under section 907(f), TPSAC must submit its report and recommendations to the Secretary within 2 years after its establishment, or March 22, 2012.

In order to provide TPSAC with the information it needs to carry out its statutory obligation, FDA is requesting that tobacco companies submit information under section 904(b) of the Tobacco Control Act (21 U.S.C. 387d(b)) pertaining to documents and underlying scientific and financial information relating to research, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on a specified set of topics. For the purposes of this request, “research” may include, but is not limited to, focus groups, surveys, experimental clinical studies, postmarketing surveillance, toxicological and biochemical assays, taste panels, and assessments of the effectiveness of product marketing practices. Topics for which information relating to dissolvable tobacco products is requested are marketing research;

marketing practices; effectiveness of marketing practices; and health, toxicological, behavioral, and physiological effects. FDA’s request for documents related to dissolvable tobacco products includes, but is not limited to products for research, investigational use, developmental studies, test marketing, and/or commercial marketing, and also to the components, parts, or accessories of such products.

In the **Federal Register** of October 25, 2010 (75 FR 65490), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received eight comments from seven commenters; six comments pertaining to the notice, and two comments pertaining to the information collection. Six comments were beyond the scope of this information request (*e.g.*, tobacco is dangerous, dissolvable tobacco products are appealing to children, FDA should let the market prevail, FDA reviewers and TPSAC are not impartial). Comments relevant to the information request are addressed in this document.

One commenter suggested that they would like to withhold proprietary information or have FDA mark the information received as “confidential and proprietary”, and would like FDA to explicitly state in the letter that FDA does not require nor accept publically available information. The commenter would like FDA to accept submission of lists, summaries, and abstracts as a first pass so FDA could then decide which documents it really needs, and would like FDA to better explain what it is looking for with regard to internal reports. The commenter would like FDA to restrict submissions to primary research data, and would like FDA to provide specific instructions for the citing of previously submitted documents so they can be fully referenced. FDA’s response is that, with regard to confidential and proprietary information, documents submitted under section 904(b) of the FD&C Act may include, but are not limited to a company’s non-public, trade secret, or confidential commercial information. FDA also notes that several laws govern maintaining the confidentiality of new tobacco product information submitted under section 904(b), including sections 301(j) and 906(c) of the FD&C Act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA’s implementing regulations. FDA’s general regulations concerning the public availability of FDA’s records are contained in 21 CFR part 20. With