

3. Regulation

a. Are there current areas of regulatory overlap among FDA, ONC, and/or FCC and if so, what are they? Please be specific if possible.

b. If there are areas of regulatory overlap, what, if any, actions should the agencies take to minimize this overlap? How can further duplication be avoided?

Dated: May 23, 2013.

Jodi Daniel,

Director, Office of Policy and Planning, Office of the National Coordinator for Health IT.

[FR Doc. 2013-12817 Filed 5-29-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the 2015 Dietary Guidelines Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS), in collaboration with the U.S. Department of Agriculture (USDA), are hereby giving notice that a meeting of the 2015 Dietary Guidelines Advisory Committee (DGAC) will be held. This meeting will be open to the public.

DATES: The meeting will be held on June 13, 2013 from 8:30 a.m.–11:30 a.m. e.d.t. and June 14, 2013 from 8:30 a.m.–3:45 p.m. e.d.t.

ADDRESSES: The meeting will be accessible by webcast on the Internet or by attendance in-person. For in-person participants, on June 13, 2013, the meeting will take place in the National Institutes of Health (NIH) Masur Auditorium. On June 14, 2013, the meeting will be held in the NIH Foundation for Advanced Education in the Sciences (FAES) Academic Center. Both facilities are located at the NIH Clinical Center, Building 10, 10 Center Drive, 9000 Rockville Pike, Bethesda, MD 20892.

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer (DFO), 2015 DGAC, Richard D. Olson, M.D., M.P.H.; Alternate DFO, 2015 DGAC, Kellie (O'Connell) Casavale, Ph.D., R.D., Nutrition Advisor; Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852; Telephone: (240) 453-8280;

Fax: (240) 453-8281; Lead USDA Co-Executive Secretary, Colette I. Rihane, M.S., R.D., Director, Nutrition Guidance and Analysis Division, Center for Nutrition Policy and Promotion, USDA; 3101 Park Center Drive, Room 1034; Alexandria, VA 22302; Telephone: (703) 305-7600; Fax: (703) 305-3300; and/or USDA Co-Executive Secretary, Shanthi A. Bowman, Ph.D., Nutritionist, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, USDA; 10300 Baltimore Avenue, BARC-West Bldg 005, Room 125; Beltsville, MD 20705-2350; Telephone: (301) 504-0619. Additional information about the 2015 DGAC is available on the Internet at www.DietaryGuidelines.gov.

SUPPLEMENTARY INFORMATION: Under Section 301 of Public Law 101-445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III) the Secretaries of Health and Human Services (HHS) and Agriculture (USDA) are directed to issue at least every five years a report titled *Dietary Guidelines for Americans*. The law instructs that this publication shall contain nutritional and dietary information and guidelines for the general public, shall be based on the preponderance of scientific and medical knowledge current at the time of publication, and shall be promoted by each federal agency in carrying out any federal food, nutrition, or health program. The *Dietary Guidelines for Americans* was issued voluntarily by HHS and USDA in 1980, 1985, and 1990; the 1995 edition was the first statutorily mandated report, followed by subsequent editions at the appropriate intervals. To assist with satisfying the mandate, a discretionary federal advisory committee is established every five years to provide independent, science-based advice and recommendations. The DGAC consists of a panel of experts who are selected from the public/private sector. Individuals who are selected to serve on the Committee must have current scientific knowledge in the field of human nutrition and chronic disease.

Appointed Committee Members: As outlined (stipulated) in the charter, the 2015 DGAC will be composed of not more than 17 members, with the minimum number being 13. Individuals are appointed to serve on the Committee who are jointly agreed upon by the Secretaries of HHS and USDA. The Secretaries of HHS and USDA recently appointed 15 individuals to serve as members of the 2015 DGAC. Information on the DGAC membership

will be available at www.DietaryGuidelines.gov.

Authority: The 2015 DGAC is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended.

Committee's Task: The work of the DGAC will be solely advisory in nature and time-limited. The Committee will develop recommendations based on the preponderance of current scientific and medical knowledge using a systematic review approach. The DGAC will examine the current *Dietary Guidelines for Americans*, take into consideration new scientific evidence and current resource documents, and develop a report to the Secretaries of HHS and USDA that outlines its science-based recommendations and rationale which will serve as the basis for developing the eighth edition of the *Dietary Guidelines for Americans*. The Committee will hold approximately five public meetings to review and discuss recommendations. Meeting dates, times, locations, and other relevant information will be announced at least 15 days in advance of each meeting via **Federal Register** notice. As stipulated in the charter, the Committee will be terminated after delivery of its final report to the Secretaries of HHS and USDA or two years from the date the charter was filed, whichever comes first.

Purpose of the Meeting: In accordance with FACA and to promote transparency of the process, deliberations of the Committee will occur in a public forum. At this meeting, the Committee will be oriented to the *Dietary Guidelines* revision process and begin its deliberations.

Meeting Agenda: The meeting agenda will include (a) review of operations for the Committee members, (b) presentations on the history of the *Dietary Guidelines* and how they are used, (c) presentation on USDA's Nutrition Evidence Library, and (d) plans for future Committee work.

Meeting Registration: The meeting is open to the public. The meeting will be accessible by webcast or by attendance in-person. Pre-registration is required for both web viewing and in-person attendance. To pre-register, please go to www.DietaryGuidelines.gov and click on the link for "Meeting Registration." To register by phone or to request a sign language interpreter or other special accommodations, please call for registration and logistics assistance through National Capitol Contracting, Laura Walters at (703) 243-9696 by 5:00 p.m. E.D.T., June 10, 2013. Pre-registration must include name, affiliation, phone number or email, days

attending, and if participating via webcast or in-person.

Webcast Public Participation: After pre-registration, individuals participating by webcast will receive webcast access information via email.

In-Person Public Participation and Building Access: For in-person participants, the meetings are within the National Institutes of Health (NIH) Clinical Center (Building 10) as noted above in the Addresses section. Details regarding registration capacity and directions will be posted on www.DietaryGuidelines.gov. For in-person participants, check-in at the registration desk onsite at the meeting is required and will begin at 7:30 a.m. each day.

Public Comments and Meeting Documents: Written comments from the public will be accepted throughout the Committee's deliberative process; opportunities to present oral comments to the Committee will be provided at a future meeting. Written public comments can be submitted and/or viewed at www.DietaryGuidelines.gov using the "Submit Comments" and "Read Comments" links, respectively. Written comments received by June 5, 2013 will ensure transmission to the Committee prior to this meeting. Documents pertaining to Committee deliberations, including meeting agendas, summaries, and transcripts will be available on www.DietaryGuidelines.gov under "Meetings" and meeting materials will be available for public viewing at the meeting. Meeting information, thereafter, will continue to be accessible online, at the NIH Library, and upon request at the Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852; Telephone (240) 453-8280; Fax: (240) 453-8281.

Dated: May 24, 2013.

Richard Olson,

Designated Federal Officer, Director, Division of Prevention Science, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

[FR Doc. 2013-12859 Filed 5-24-13; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Health Resources and Services Administration

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

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) and the Health Resources and Services Administration (HRSA) announce the following meeting of the aforementioned committee:

Times and Dates: 8:00 a.m.–5:30 p.m., June 18, 2013; 8:00 a.m.–2:30 p.m., June 19, 2013.

Place: CDC Corporate Square, Building 8, Conference Room 1-ABC, 8 Corporate Boulevard, Atlanta, Georgia 30329, Telephone: (404) 639-8317.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people. This meeting is also accessible by teleconference. Toll-free +1 (866) 718-4584, Participant code: 8484551.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

Purpose: This Committee is charged with advising the Director, CDC and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS, Viral Hepatitis and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS, Viral Hepatitis and other STDs.

Matters To Be Discussed: Agenda items include: (1) STD clinical preventive services in primary care setting and integrating STD screening and treatment services in HIV care settings); (2) The test and cure era for hepatitis C: The public health response to rising hepatitis C mortality; The impact of new therapies on health outcomes; and Building care capacity to increase access to hepatitis C virus (HCV) therapy; (3) HIV Medical Monitoring Project: follow up on Institute of Medicine (IOM) report and other Affordable Care Act (ACA) issues; (4) Recommendations for new HIV diagnostic laboratory testing algorithms; and (5) CHAC Workgroups Update.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Margie Scott-Cseh, Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 1600 Clifton Road NE., Mailstop E-07, Atlanta, Georgia 30333, Telephone (404) 639-8317.

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.

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

Food and Drug Administration

[Docket No. FDA-2013-N-0577]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

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 information collection contained in the requirements for the submission of labeling for human prescription drugs and biologics in electronic format.

DATES: Submit either electronic or written comments on the collection of information by July 29, 2013.

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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, 301-796-7726, Ila.mizrachi@fda.hhs.gov.