substantial equivalence (sections 905(j) and 910 of the FD&C Act, as amended by the Tobacco Control Act (21 U.S.C. 387e(j) and 387j)). In this draft guidance, FDA provides responses to questions related to the submission of 905(j) (substantial equivalence) reports in specific scenarios, including questions on whether changes to packaging and labeling and changes to additive specifications should be submitted in a 905(j) report to the Center for Tobacco Products. The draft guidance also provides information about discussing submissions.

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.'' 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

An electronic version of the draft guidance document is available on the Internet at *http://www.regulations.gov and http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 905(j) and 910 of the FD&C Act, as amended by the Tobacco Control Act have been approved under OMB control number 0910–0673; the collections of information in 21 CFR part 25 have been approved under OMB control number 0910–0322.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23100 Filed 9–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Food and Drug Administration Health Professional Organizations Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA) is announcing a conference for representatives of Health Professional Organizations. Dr. Margaret Hamburg, Commissioner of the Food and Drugs, and Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research have been invited to speak about their visions of the relationship between the Agency and the health professional community. Other topics on the agenda include Risk Evaluation and Mitigation Strategies and the Unapproved Drugs Initiative.

Date and Time: The conference will be held on October 31, 2011, from 8 a.m. to 1:30 p.m.

Location: The conference will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002.

Contact Person: For further information contact Janelle Derbis, Office of Special Health Issues, 10903 New Hampshire Ave., Silver Spring, MD 20993, 312–596–6516, Fax: 312–886–1682, *Janelle.Derbis@fda.hhs.gov.*

Registration: Register at *http://www.cvent.com/d/fcq7vv/4W* by October 7, 2011. Please include the name and title of the person attending, the name of the organization, address, and telephone number. There is no registration fee for this conference. Early registration is suggested because space is limited. We request that organizations limit the number of representatives to two. For further registration information, call 1–866–318–4357.

SUPPLEMENTARY INFORMATION: The aim of the conference is to further the public health mission of the FDA through training, collaboration, and structured discussion between health professional organizations and FDA staff. The Office of Special Health Issues serves as a liaison between the FDA Centers and the public on matters that involve medical product safety and also acts as the public's link to information about the medical product approval process.

The topics of discussion for this conference will include three separate panels that will highlight examples where FDA and health professional organizations collaborate to further public health. The goal of the panel presentations is to exchange ideas, highlight the value of FDA and health professional organizations working together, and encourage collaboration to promote public health. A list of concurrent breakout session topics is included in the agenda to facilitate informal discussion on how FDA and health professional organizations can collaborate more effectively. Please indicate during your registration the topics of greatest interest to you for the breakout session.

If you need special accommodations due to a disability, please contact Janelle Derbis at least 7 days in advance.

Dated: September 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23101 Filed 9–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Conflicts and Eating Disorders.

Date: October 4, 2011.

Time: 3 p.m. to 5 p.m.