Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23099 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–D–0376]

Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period by 60 days to December 2, 2011, for the notice entitled ''Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability,'' that appeared in the **Federal Register** of July 5, 2011 (76 FR 39111). In that document, FDA announced the availability of a draft guidance for industry and requested comments. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by December 2, 2011.

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Corey Hilmas, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 5, 2011 (76 FR 39111), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry entitled ''Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.'' Comments on the draft guidance will assist FDA in the development of final guidance for industry on new dietary ingredient notifications and related issues.

The Agency has received a request for a 45-day extension of the comment period for this notice. FDA has considered the request and is extending the comment period for the notice entitled ''Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability,'' until December 2, 2011. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying action by the Agency.

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23098 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–D–0147]

Draft Guidance for Industry and Food and Drug Administration Staff; Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions; 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 ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.'' This draft guidance provides responses to questions FDA has received on the Family Smoking Prevention and Tobacco Control Act's (Tobacco Control Act) provisions on new tobacco products and substantial equivalence, including questions on changes to packaging and labeling. This draft guidance is not final nor is it in effect at this time.

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 of 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 8, 2011.

ADDRESSES: 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.

Submit written requests for single copies of the draft guidance document entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, *annette.marthaler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides responses to questions we have received on the Federal Food, Drug, and Cosmetic Act's (the FD&C Act) provisions on new tobacco products and

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.