

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2009-D-0542]

Draft Guidance for Industry: Factors That Distinguish Liquid Dietary Supplements From Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods." The draft guidance describes factors that can be used to identify liquid products that are excluded from being dietary supplements because they are represented as conventional foods. Further, the draft guidance reminds manufacturers and distributors of beverages and other conventional foods, particularly those that contain novel ingredients, about the requirements of the Federal Food, Drug, and Cosmetic Act (the act) regarding ingredients and labeling.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by February 2, 2010.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Robert Moore, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2375.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft guidance entitled "Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods." The draft guidance is intended to assist dietary supplement and beverage manufacturers and distributors in reaching a determination as to whether a liquid product may be labeled and marketed as a dietary supplement. The draft guidance describes factors that manufacturers and distributors can use to identify liquid products that are excluded from being dietary supplements because they are represented as conventional foods. Further, the draft guidance reminds manufacturers and distributors of beverages and other conventional foods, particularly those that contain novel ingredients, about the requirements of the act regarding ingredients and labeling.

FDA is issuing this draft guidance as Level 1 guidance 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 the topics discussed. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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 <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>.

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Dated: November 30, 2009.

David Horowitz,*Assistant Commissioner for Policy.*

[FR Doc. E9-28926 Filed 12-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

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 meeting.

The meeting 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 Allergy and Infectious Diseases Special Emphasis Panel; SARS Replication.

Date: January 19, 2010.*Time:* 11:30 a.m. to 4:30 p.m.*Agenda:* To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call)

Contact Person: Brenda Lange-Gustafson, PhD, Scientific Review Officer, NIAID/NIH/DHHS, Scientific Review Program, Room 3122, 6700-B Rockledge Drive, MSC-7616, Bethesda, MD 20892-7616, 301-451-3684, bgustafson@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 30, 2009.

Jennifer Spaeth,*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-29010 Filed 12-3-09; 8:45 am]

BILLING CODE 4140-01-P