

Model Programs, RFA OH-00-007, and Development of New or Enhanced Models for State-Based Occupational Surveillance, RFA OH-00-008.

Times and Dates: 8 a.m.–8:30 a.m., August 2, 2000 (Open).

8:30 a.m.–5 p.m., August 2, 2000 (Closed).

8 a.m.–5 p.m., August 3, 2000 (Closed).

Place: Embassy Suites, 1900 Diagonal Road, Alexandria, Virginia 22314.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92-463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to RFA-OH-00-007 and RFA OH-00-008.

Contact Person for More Information: Michael J. Galvin, Jr., Ph.D., Health Science Administrator, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, 1600 Clifton Road, N.E., m/s D30 Atlanta, Georgia 30333. Telephone 404/639-3525, e-mail mtg3@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: July 7, 2000.

Julia M. Fuller,

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

[FR Doc. 00-17700 Filed 7-12-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1360]

Draft Guidance for Industry: Food-Contact Substance Notification System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Preparation of Premarket Notifications for Food Contact Substances: Administrative." This document is intended to provide guidance for industry regarding the preparation of premarket notifications for food-contact substances (FCS). FDA is providing this draft guidance as part

of its implementation of the premarket notification process for FCS established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments on this draft guidance by September 26, 2000 to ensure their adequate consideration in the preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Preparation of Premarket Notifications for Food Contact Substances: Administrative" to the Office of Premarket Approval (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. The document may also be obtained by calling the Office of Premarket Approval at 202-418-3080 or by fax at 202-418-3131. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3083.

SUPPLEMENTARY INFORMATION:

I. Background

FDAMA (Public Law 105-115) amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a premarket notification (PMN) process as the primary method for authorizing new uses of food additives that are FCS. A "food contact substance" is defined in section 409(h)(6) of the act as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." FDA expects most new uses of FCS that previously would have been regulated by issuance of a listing regulation in response to a food additive petition or would have been exempted from the requirement of a regulation under the threshold of regulation process (21 CFR 170.39) will be the subject of PMN's. FDA is announcing the availability of a draft guidance document entitled "Preparation of Premarket Notifications for Food Contact Substances: Administrative." This document is

intended to provide guidance for industry regarding the preparation of premarket notifications for FCS. FDA is providing this draft guidance as part of its implementation of the premarket notification process for FCS established by FDAMA. Elsewhere in this issue of the **Federal Register** FDA is proposing regulations necessary to implement the notification process for FCS.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the data and information that should be submitted in a premarket notification for the use of a FCS. This draft guidance document 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.

This draft guidance document is a level 1 guidance under the agency's good guidance practices (62 FR 8961, February 27, 1997).

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document by September 26, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Such comments will be considered when determining whether to amend the draft guidance.

VI. Electronic Access

The draft guidance may also be accessed on the Internet site for the Center for Food Safety and Applied Nutrition at <http://www.cfsan.fda.gov>.

Dated: June 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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