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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**Draft Guidance for Industry: Food-Contact Substance Notification System; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Preparation of Premarket Notifications for Food Contact Substances: Administrative."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 FDA is providing this draft guidance as part of its implementation of the premarket notification process for FCS established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Submit written comments on this draft guidance by [insert date 75 days after date of publication in the **Federal Register**] to ensure their adequate consideration in the preparation of the final document.

**ADDRESSES:** Submit written requests for single copies of the draft guidance entitled "Preparation of Premarket Notifications for Food Contact Substances: Administrative" to the Office of Premarket Approval (HFS-200), Food and Drug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Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

NAD 1

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**

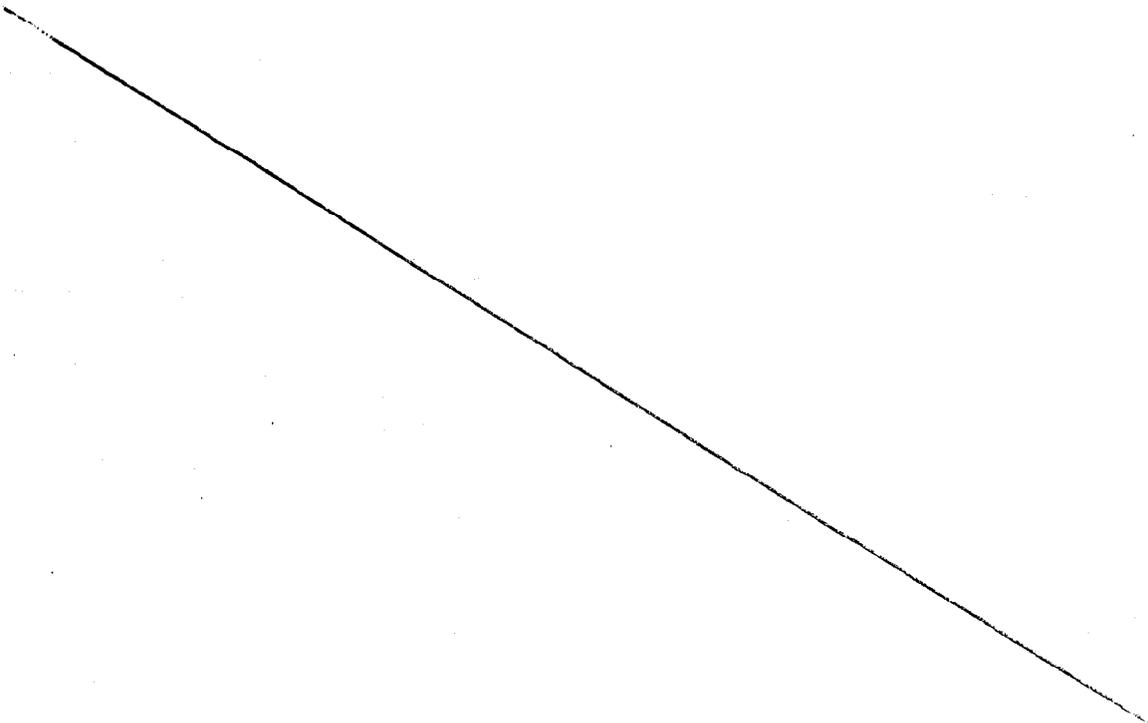
This draft guidance document represents the agency’s current thinking on the data and information that should be submitted in a premarket notification for the use of a FCS. This draft

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**

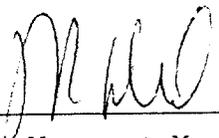
Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document by [*insert date 75 days after date of publication in the **Federal Register***]. Two copies of any comments are to be submitted, except that individuals may submit one 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.



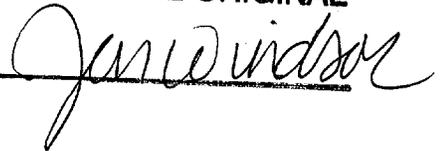
**VI. Electronic Access**

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: 6/27/00  
June 27, 2000

  
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Margaret M. Dotzel,  
Associate Commissioner for Policy.

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

  
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[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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