

DmB

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

Display Date 4-10-02  
Publication Date 4-11-02  
Certifier A. Corbin

[Docket Nos. 99D-4575 and 99D-4576]

**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 two final guidance documents entitled: "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations" and "Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations." These guidance documents are intended to provide guidance for industry regarding the preparation of food contact notifications (FCNs) and petitions for food contact substances (FCSs). FDA is providing these guidance documents as part of its implementation of the FCN process established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Submit written or electronic comments on these guidance documents at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance documents to the Office of Food Additive Safety (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on these guidance documents to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. You also may request a copy of the guidance documents by electronic mail at [OPAPMN@CFSAN.FDA.GOV](mailto:OPAPMN@CFSAN.FDA.GOV), or by telephone to the Office of Food Additive Safety at 202-418-3087 (voice) or FAX 202-418-3131. All requests should identify the guidance documents

by the titles listed in the **SUMMARY** section. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

**FOR FURTHER INFORMATION CONTACT:** Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3083.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish the FCN process as the primary method for authorizing new uses of food additives that are FCSs. An FCS 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 FCSs 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 will be the subject of FCNs. FDA is announcing the availability of two final guidance documents entitled: “Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendation” (Docket No. 99D-4575) and “Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations” (Docket No. 99D-4576). These documents are intended to provide guidance for industry regarding the preparation of FCNs. FDA is providing these final guidance documents as part of its implementation of the FCN process established by FDAMA.

**II. Significance of Guidance**

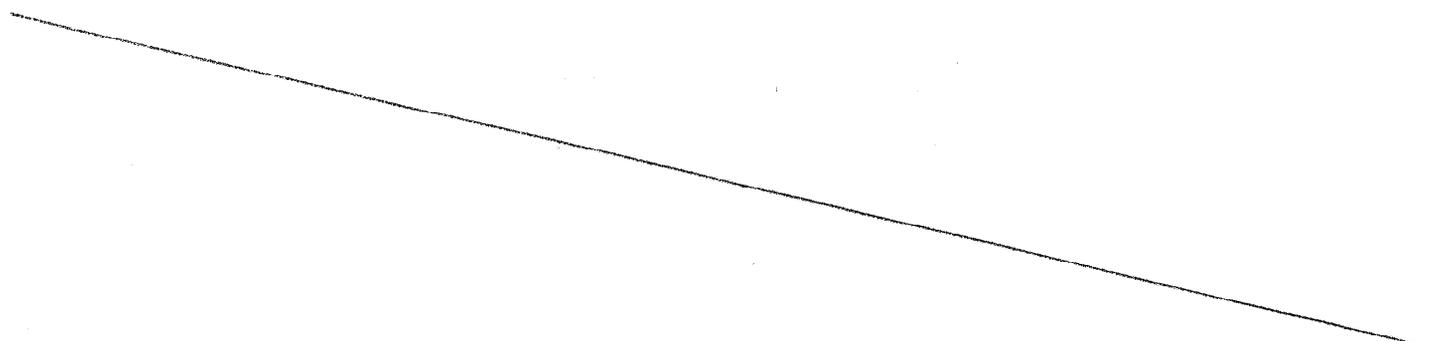
These two final guidance documents represent the agency’s current thinking on the data and information that should be submitted in an FCN. These guidance documents do not create or confer

any rights for or on any person and do 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. These two guidance documents are level 1 guidance under the agency's good guidance practices (GGPs) regulation (21 CFR 10.115).

Because they are level 1 guidance under the agency's GGPs, FDA announced the availability of these two guidance documents entitled: "Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations" and "Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations" in draft form for comment in a notice published in the **Federal Register** of November 12, 1999 (64 FR 61648). The comment period for these two draft guidance documents closed on February 14, 2000. FDA received two comments on the draft guidance documents which it has addressed in the final guidance documents being made available by this notice. Thus, in accordance with its GGPs, FDA is now reissuing these two guidance documents in final form. The final guidance documents have different titles than the draft guidance documents made available in the November 12, 1999, notice.

### **III. Comments**

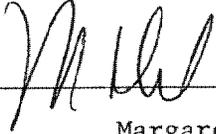
Interested persons may, at any time, submit written comments regarding the guidance documents to the Dockets Management Branch (see **ADDRESSES** section for address). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the appropriate docket numbers found in brackets in the heading of this document. The guidance documents and received comments may be examined in the office above between 9 a.m. and 4 p.m., Monday through Friday.



**IV. Electronic Access**

The guidance also may be accessed on the Internet site for the Center for Food Safety and Applied Nutrition (CFSAN) listing all CFSAN guidances at <http://www.cfsan.fda.gov/~dms/guidance.html>.

Dated: 3/29/02  
March 29, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 02-???? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

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

