

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1360]

DMB
Display Date 5-22-00
Publication Date 5-22-00
Certifier R. LEDESMA

Guidance for Industry on Preparation of Food Contact Notifications: Administrative; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Preparation of Food Contact Notifications: Administrative." This guidance document is intended to provide guidance for industry regarding the preparation of food contact notifications (FCNs). FDA is providing this guidance as part of its implementation of the premarket notification process for food contact substances (FCSs) established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments concerning this guidance document at any time.

ADDRESSES: Submit written comments concerning this guidance document 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>. Submit written requests for single copies of the guidance document 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. You also may request a copy of the guidance document by electronic mail at OPAPMN@CFSSAN.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 be identified with the guidance

cf00125

00D-1360

NAD-2

document by its title. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

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 an FCN process as the primary method for authorizing new uses of food additives that are FCSs. 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 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 the guidance document entitled “Preparation of Food Contact Notifications: Administrative.” This guidance document is intended to provide guidance for industry regarding the preparation of FCNs. FDA is providing this guidance document as part of its implementation of the premarket notification process for FCSs established by FDAMA.

II. Significance of Guidance

This guidance document represents the agency’s current thinking on the data and information that should be submitted in an FCN and the plan for administration of the FCN program. This 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 guidance document is a level 1 guidance under the agency's good guidance practices (GGPs) regulations (21 CFR 10.115).

Because it is a level 1 guidance under the agency's GGPs, FDA announced the availability for comment of a draft of the guidance document "Preparation of Food Contact Notifications: Administrative" in a notice published in the **Federal Register** of July 13, 2000 (65 FR 43377). The comment period for the guidance document closed on September 26, 2000. FDA received no comments on the guidance document. However, FDA did receive three comments on the proposed rule published simultaneously with the July 13, 2000, notice of availability. Portions of these three comments are relevant to the guidance document and FDA has addressed the relevant portions of the comments in the guidance document announced by this notice. Thus, in accordance with its GGPs, FDA now is reissuing this guidance document in final form.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.cfsan.fda.gov/~dms/guidance.html>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written and electronic comments regarding the guidance document at any time. 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 guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Such comments will be considered when determining whether to amend the guidance.

Dated: 5/6/02
May 6, 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**



Regina Sedesova