

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

1805 '03 JUN -5 P3:38

[Docket No. 2003N-0224]

DMB Immediate Display

Display Date *6-5-03@2:50pm*

Publication Date *6-10-03*

Certifier *Dr. Hawkins*

Premarket Notification for Food Contact Substances; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: FDA Workshop on the Notification Process for Food Contact Substances. The purpose of the meeting is to discuss the food contact notification (FCN) process so that notifiers and/or their representatives, consumer interest groups, and other interested members of the general public can have a better understanding of the FCN process, the information requirements of an FCN, and the common deficiencies to be avoided.

DATES: The meeting will be held on Wednesday, June 25, 2003, from 11:30 a.m. to 2:30 p.m.

ADDRESSES: The meeting will be held at the Hyatt Regency Chicago, 151 East Wacker Dr., Chicago, IL.

FOR FURTHER INFORMATION CONTACT: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3088, FAX: 202-418-3131, or e-mail: wjt@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In November 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 309 of FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a notification process for food contact substances (FCSs). An FCS is defined 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 a technical effect in such food” (21 U.S.C. 348(h)(6)). The FCN process is used to authorize the marketing of an FCS except where the Secretary determines that submission of a food additive petition is necessary or the Secretary and a manufacturer or supplier agree that a food additive petition may be submitted (21 U.S.C. 348(h)(3)(A)).

Under 21 U.S.C. 348(h), the notification process requires a manufacturer or supplier of an FCS to notify FDA at least 120 days prior to the introduction or delivery for introduction in interstate commerce of an FCS. If FDA does not object to the notification within 120 days, the notification becomes effective (21 U.S.C. 348(h)(2)(A)), and the substance may be legally marketed for the requested use by the notifier (21 U.S.C. 348(a)(3)(B)).

In the **Federal Register** of May 21, 2002 (67 FR 35724), FDA published a final rule amending the food additive regulations regarding the premarket notification process for FCSs. The rule became effective on June 20, 2002, and requires that a notification for an FCS contain sufficient scientific information to demonstrate that the FCS that is the subject of the notification is safe for the intended use (21 CFR 170.101). Since the inception of the FCN process in 1999, FDA has found that FCNs frequently have deficiencies which cause them to be incomplete. FDA is having this public meeting to discuss the data

requirements for an FCN and the commonly observed deficiencies and to assist notifiers and/or their representatives in submitting adequate and complete FCNs.

II. Registration and Written Questions

Persons interested in attending the June 25, 2003, meeting should send their registration information (including name, title, business affiliation, address, and telephone and fax number) to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To expedite processing, registration information may also be faxed to 202-418-3131 or e-mailed to wjt@cfsan.fda.gov. There will be no registration charges for attending the meeting. If you need special accommodations due to disability, please notify the contact person by June 13, 2003.

III. Availability of Guidance Documents for FCNs

Administrative, chemistry, and toxicology guidance documents for FCNs are available at the following Web site: <http://www.cfsan.fda.gov/~dms/opa-notf.html>.

IV. Agenda and Goals

FDA will present its recommendations for information necessary to make an FCN adequate and complete. Topics to be presented will be broadly divided among the general categories of administrative, chemical, toxicological, and environmental information. The agenda will include the following items:

(1) Administrative: guidance document, an overview of the review process, common FCN deficiencies, Form 3480, confidentiality, one FCS per FCN, and conditions under which a food additive petition should be submitted;

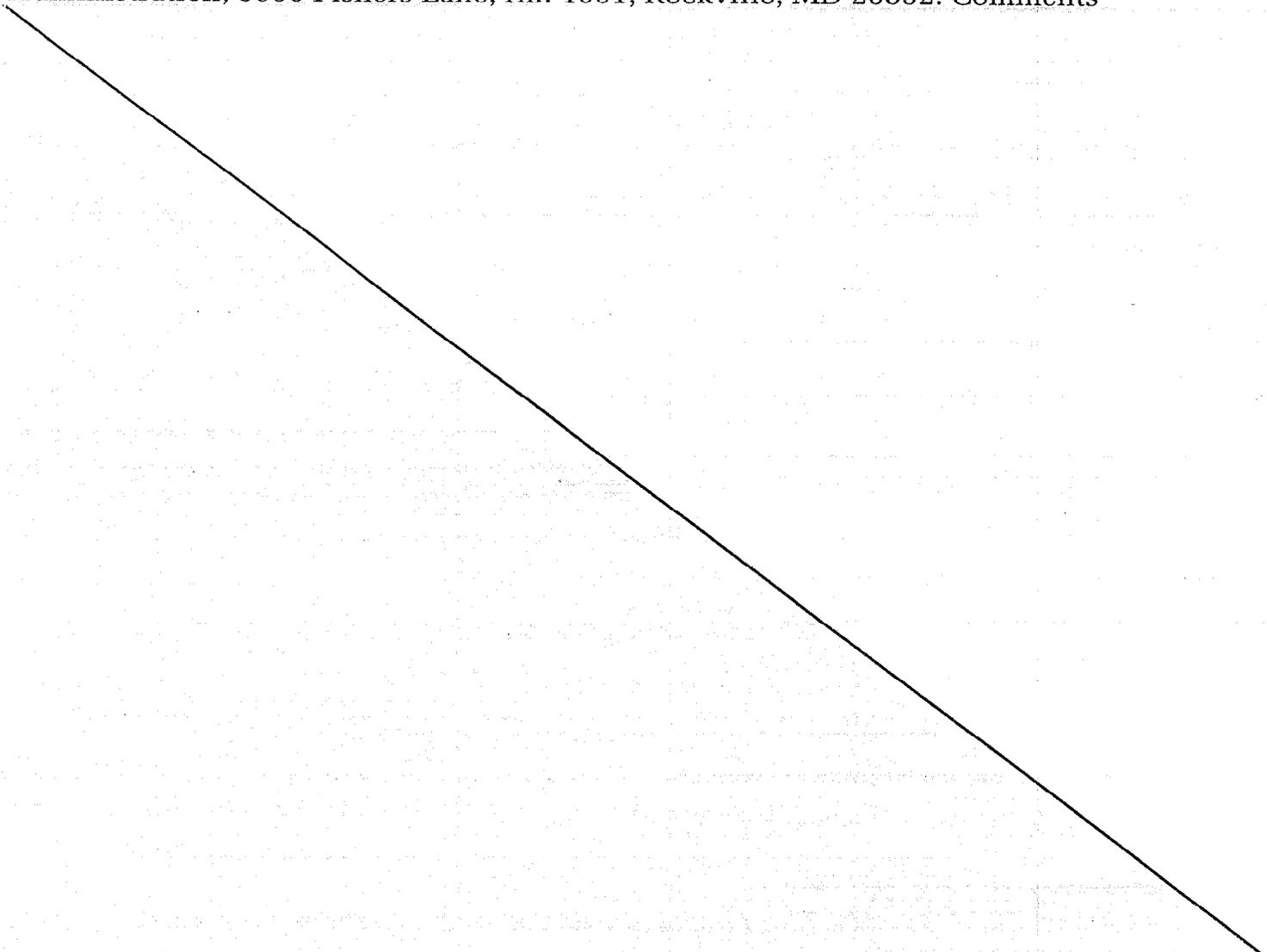
(2) Chemical: guidance document, common FCN deficiencies, approaches for determining migrant levels in food, estimated daily intake, and cumulative estimated daily intake;

(3) Toxicological: guidance document, common FCN deficiencies, acceptable daily intake, risk assessments, structure activity relationships, and recommended testing; and

(4) Environmental: requirements, common FCN deficiencies, categorical exclusions, and requirements for an environmental assessment.

V. Comments

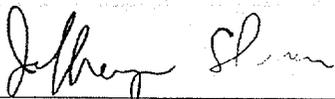
Written comments regarding the agenda may be submitted and should be identified with the docket number found in brackets in the heading of this document. Comments should be annotated and organized to identify the specific issues to which they refer. These comments should be submitted by June 13, 2003, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments



may also be sent to the Dockets Management Branch at the following e-mail address: fdadockets@oc.fda.gov or via the FDA Web site at <http://www.fda.gov>.

Dated: JUN 5 2003

June 5, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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