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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	J. W. [Signature]

Food and Drug Administration

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

**Draft Guidances for Industry on 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidance documents entitled "Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations," and "Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations." These documents are intended to provide guidance for industry regarding the preparation of premarket notifications (PMN's) for food-contact substances (FCS's). In addition, FDA Form No. 3480 entitled "Notification for New Use of a Food Contact Substance" is being made available as an attachment to each of these guidance documents. This form is provided for comment as part of the collection of information for the notification system for FCS's. FDA is providing these draft guidances as part of its implementation of the PMN process for FCS's established by the FDA Modernization Act of 1997 (FDAMA) (Public Law 105-115).

DATES: Submit written comments concerning these draft guidances by (*insert date 90 days after date of publication in the Federal Register*). Submit written comments concerning the collection of information by (*insert date 60 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments concerning these draft guidances and the collection of information 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 cf99151

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number found in brackets in the heading of this document. Submit written requests for single copies of the draft guidances to the Office of Premarket Approval (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3100, FAX 202-418-3131. All requests should identify the draft guidances by the titles listed above. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these draft guidances.

FOR FURTHER INFORMATION CONTACT: Mitchell A. 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 amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a PMN process as the primary method for authorizing new uses of food additives that are FCS's. 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." Once the PMN process begins to operate (see section 409(h)(5) of the act), FDA expects most new uses of FCS's that previously would have been regulated by issuance of a listing regulation in response to a food additive petition (FAP) or would have been exempted from the requirement of a regulation under the threshold of regulation (TOR) process will be the subject of PMN's. FDA is announcing the availability of two draft guidance documents entitled "Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations," and "Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations." These documents are intended to provide guidance for industry regarding the preparation of PMN's for FCS's. FDA is providing these draft guidances as part of its implementation of the PMN process for FCS's established by FDAMA.

II. Significance of Guidance

These two draft guidance documents represent the agency's current thinking on the data and information that should be submitted in a PMN for the use of an FCS. These draft 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 draft guidance documents are level 1 guidances under the agency's good guidance practices (62 FR 8961, February 27, 1997).

III. Electronic Access

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

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Food-Contact Substances Notification System

Description: Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) establishes a premarket notification process for FCS's. Section 409(h)(6) of the act defines a "food contact substance" 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." Section 409(h)(3) of the act requires that the notification process be utilized for authorizing the marketing of FCS's, except where FDA determines that the submission and premarket review of an FAP under section 409(b) of the act is necessary to provide adequate assurance of safety. Section 409(h)(1) of the act requires that a notification include information on the identity and the intended use of the FCS and the basis for the notifier's determination that the FCS is safe under the intended conditions of use. Because section 409(h)(1) of the act references the general safety standard for food additives, the data in a PMN should be comparable to the data in an FAP. FDA is announcing the availability for comment of two draft guidance documents that are part of the agency's implementation of the PMN program, which will largely replace the FAP process for those food additives that are FCS's. The information to be collected is information on the manufacture and intended use of the FCS, studies relating to the safety of the FCS, and other information necessary to demonstrate that the FCS is safe under the intended conditions of use.

FDA is also making available for comment FDA Form No. 3480 entitled "Notification for New Use of a Food Contact Substance" for a notification for a new use of a FCS. FDA believes that this form will facilitate both preparation and review of notifications since the form will serve to organize information necessary to support the safety of the use of the FCS. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Description of Respondents: Manufacturers of food-contact substances.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3480 ²	200	1	200	25	5,000
FDA 3480 ³	125	2	250	120	30,000
FDA 3480 ⁴	45	2	90	150	13,500
FDA 3480 ⁵	16	1	16	150	2,400
Total					50,900

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Duplicate notifications for uses of FCS's.

³ Notifications for uses that would currently be the subject of exemptions under 21 CFR 170.39 or very simple FAP's.

⁴ Notifications for uses that would currently be the subject of moderately complex FAP's.

⁵ Notifications for uses that would currently be the subject of more complex FAP's.

The above estimate is based on the types of submissions that FDA currently receives for FCS's in the TOR and the FAP processes and the following assumptions and information:

1. FDA estimates that the likely increase in PMN's over the number of FAP's and TOR requests will be approximately four times the highest recent influx of these submissions (50 and 54, respectively). This factor is based on an analysis of the number of companies producing various types of FCS's and the types of FCS's for which FAP's and TOR's are most commonly submitted to FDA.

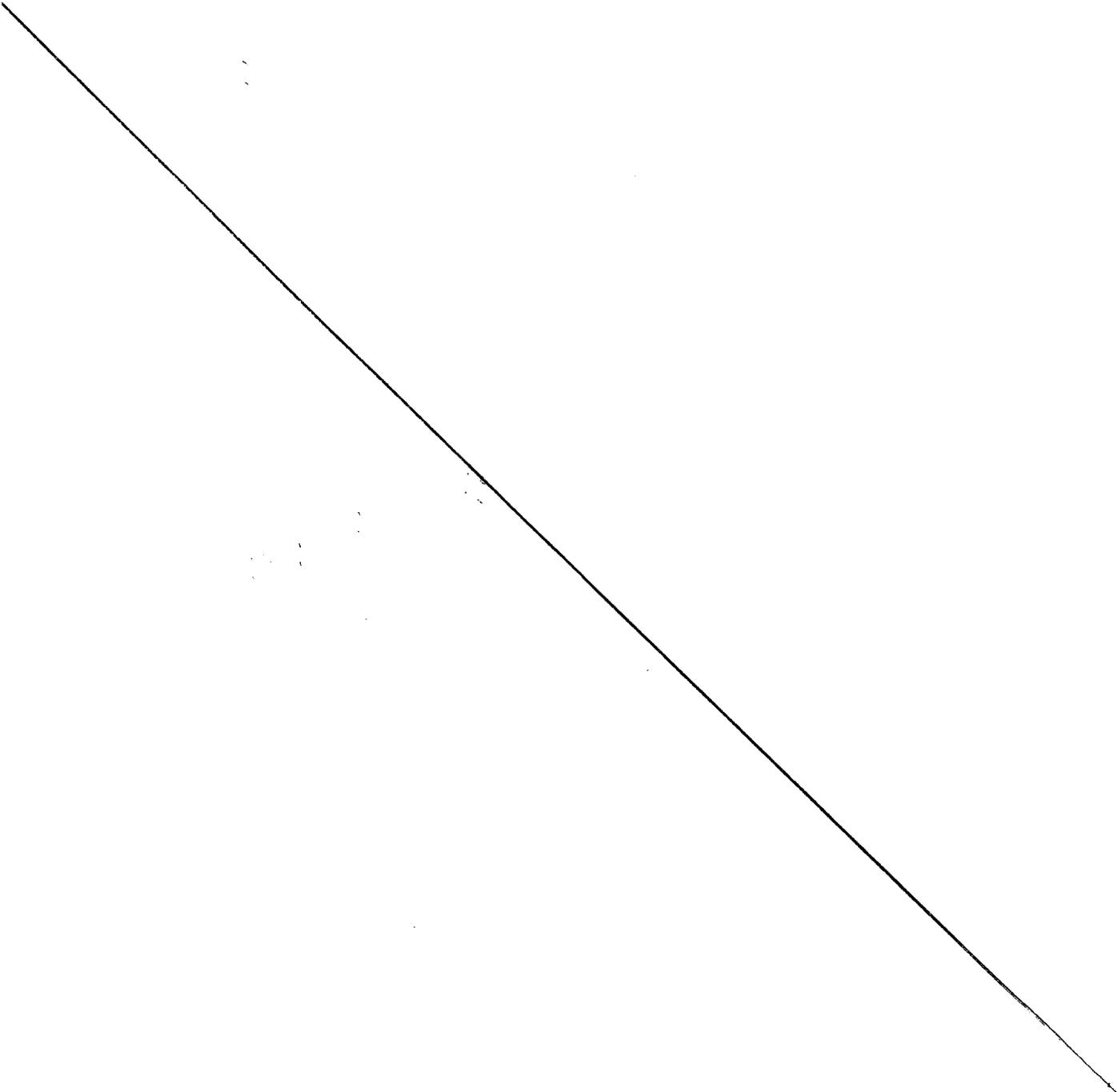
2. FDA also has included 200 expected duplicate submissions in the second lowest tier. FDA expects that the burden for preparing these notifications will primarily consist of the notifier filling out FDA Form No. 3480, verifying that a previous notification is effective, and preparing necessary documentation.

3. Based on the amount of data typically submitted in FAP's and TOR requests, FDA identified three other tiers of PMN's that represent escalating levels of burden required to collect information.

4. FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers, and the cost of developing necessary data based on input from industry sources.

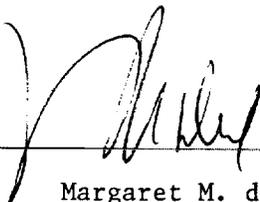
V. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding the two draft guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. Submit written comments concerning this collection of information to the Dockets Management Branch by (*insert date 60 days after*

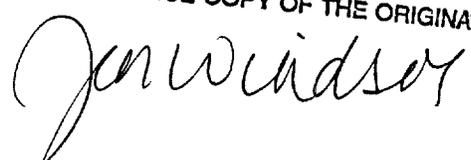


date of publication in the **Federal Register**). The draft guidance documents and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered when determining whether to amend the guidance.

Dated: 1/1/99
November 1, 1999



Margaret M. dotzel
Acting Associate Commissioner
for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL


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