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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food-Contact Substance Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Title: Food-Contact Substances Notification System

Description: Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)) establishes a premarket notification (PMN) process for food-contact substances (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 a food additive petition (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.

In the **Federal Register** of November 12, 1999 (64 FR 61648), FDA announced 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 also made available for comment FDA Form No. 3480, entitled "Notification for New Use of a Food Contact Substance," which is to be used for a notification for a new use of a FCS. FDA believes that this form will facilitate both preparation and review of notifications because 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. The agency requested comments on the proposed collections of information.

One comment was received on FDA's paperwork reduction analysis for the notification program for FCS's. Portions of this comment concern the content of the guidance documents announced in the November 12, 1999, notice. FDA will consider these portions of the comment in preparing the final version of the guidance documents.

Portions of the comment addressed the format, content, and utility of the proposed FDA Form 3480. The comment stated that FDA Form 3480 would be more useful if it were made available in a common word processor format such as WordPerfect® or Word®. FDA has made the form available in a portable document format that is compatible with and can be read by most current versions of word processing software packages. Therefore, FDA disagrees that it is necessary for the form to be available in a word processor format in order for it to be useful. However, FDA does expect to make the form available in WordPerfect® and Word® formats once the form has been approved by OMB.

The comment further stated that the form should be pilot tested to insure its compatibility throughout the industry. FDA has designed Form 3480 to function as summary form for many types of notifications. FDA expects to modify the form to suit the needs of the agency and the various types of notifications and notifiers. FDA expects to make it possible for notifiers to fill out the form through the agency's Internet site, and to ultimately use the form to facilitate electronic submissions. FDA believes that the most efficient way to evaluate this form is to begin using it and examine the problems and any suggestions for improvement on a continuing basis. FDA expects to accomplish this through the periodic reauthorization of the form required by OMB.

The comment correctly states that, in many cases, only summary information may be included in the form and that more detailed information will need to be referenced and attached. Moreover, the comment states that this caused the form to be a many-segmented document forcing the reader to jump back and forth within the document. The comment also states that a summary form with all supporting information attached in a specified format would be more useful to FDA and the regulated industry. The comment further states that all notifications should contain the same information in the same place within the submission.

As explained above, FDA believes that FDA Form 3480 is the summary form that the comment suggests is needed. FDA has not mandated, and does not expect to mandate, a particular format for notifications in regulations. Therefore, notifiers are free to present and organize the

supporting information exactly as the notifier wishes. FDA recognizes that all sections of FDA Form 3480 will not be applicable to all notifications nor to all notifiers. However, FDA believes that most if not all notifiers will find the form useful in organizing their submissions. In addition, FDA disagrees with the notifier that the form will not assist FDA in processing notifications because it will be a many-segmented document. FDA's review of notifications is generally segmented into chemical, toxicological, and environmental disciplines. FDA Form 3480 was designed with this review process in mind. The proposed Form 3480 will assist FDA reviewers in locating the pertinent portions of the data and information that relate specifically to their discipline and their specific review responsibilities.

Description of Respondents: Manufacturers of food-contact substances.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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	55	2	110	120	13,200
FDA 3480 ⁴	45	2	90	150	13,500
FDA 3480 ⁵	16	1	16	150	2,400
Total					34,100 ⁶

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.

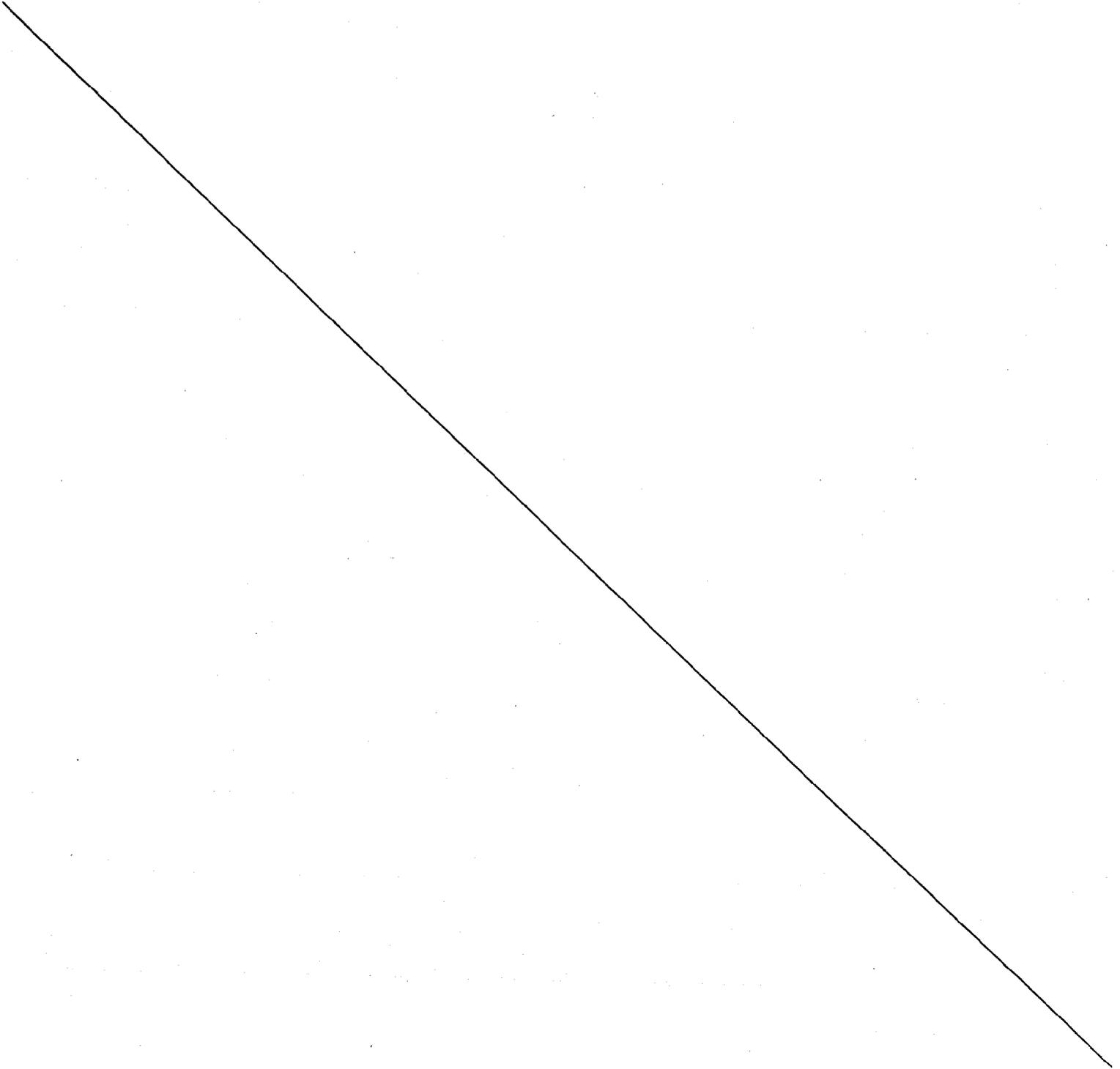
⁶ Due to a clerical error, the reporting burden hours for FDA 3480³ that appeared in the FEDERAL REGISTER of November 12, 1999 (64 FR 61648), were incorrect. Table 1 of this document contains the correct estimates.

The above estimate is based on the types of submissions that FDA currently receives for FCS's in the threshold of regulation (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.

Dated: May 23, 2000



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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