

Supporting Statement
Food Contact Substances Notification System

1. Circumstances Necessitating Information Collection

In 1958, Congress amended the Federal Food, Drug, and Cosmetic (FD&C) Act to require premarket authorization of food additives (21 U.S.C. 321(s), 342(a)(2)(C), and 348). A "food additive," as defined in section 201(s) of the Act, is:

* * * any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food;***), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been shown through scientific procedures *** to be safe under the conditions of its intended use***.

Because the definition of a food additive includes substances that may reasonably be expected to "indirectly" become a component of food, food additives that are components of food contact materials require premarket authorization. In November 1997, section 309 of the Food and Drug Administration Modernization Act (FDAMA) amended section 409 (Attachment 1) of the FD&C Act establishing a premarket notification process for "food contact substances". FDAMA added a definition for a "food contact substance" under section 409(h)(6) of the FD&C Act as follows:

the term "food contact substance" means 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.

Under section 409(h) of the FD&C Act, manufacturers and suppliers of food contact substances are required to notify FDA 120 days prior to marketing a food contact substance for a new use. Under section 409(h)(1), such notifications must include information on the identity and intended use of the food contact substance, the notifier's determination that the intended use of the food contact substance is safe, all information that forms the basis for that determination, and any information that FDA requires by regulation to be provided.

Under section 409(h)(3)(A) of the FD&C Act, premarket notifications for food contact substances are intended to be the primary method for authorizing the use of food contact substances. The only other methods for authorizing a new use of a food contact substance are the food additive petition process (Section 409(b) of the FD&C Act) and FDA's threshold of regulation process (21 CFR

170.39). These other processes require the same level of information to support the safe use of a food contact substance that comparable premarket notifications would require. However, the food additive petition and threshold of regulation processes are more burdensome on industry than the notification process, because the petition and threshold processes do not require automatic authorization within a specific time frame.

This is a request for OMB approval of the information collection requirements in the guidance documents (Attachment 2) "Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations", "Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations" and FDA Form 3480.

Information required in a notification for a food contact substance that provides a basis for estimating daily dietary exposure to the substance resulting from its notified use. Such a notification must also either contain data from toxicological studies which demonstrate that the daily dietary exposure to the food contact substance does not pose a safety hazard or must reference such data in FDA files.

2. How, by Whom, and for What Purpose Information is Used

Notifications for food contact substances submitted by manufacturers are reviewed by FDA scientific personnel to ascertain if the data establish the identity of the substance, its use in contact with food, and support the notifier's determination that the intended use in contact with food is safe. Section 409(h)(4) of the FD&C Act requires FDA to keep confidential any information submitted in a premarket notification for the entire 120-day review period. If FDA does not object to the notification within 120 days after receipt, the notification becomes effective and the substance may be legally marketed. No action is required by FDA for a notification under section 409(h) of the FD&C Act to become effective, and FDA is not required by statute to publish a notice that a notification is effective or to inform the notifier in writing that a notification has become effective.

3. Consideration of Information Technology

In a **Federal Register** notice of August 31, 1994 (59 FR 45160), FDA proposed regulations that would, under certain circumstances, permit the agency to accept electronic records, electronic signatures, and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These proposed regulations would apply to notifications submitted under section 409(h) of the FD&C Act.

The agency currently has a working local area network (LAN) and optical scanning system in operation. Current paper files are optically scanned and placed on the LAN. This is a preliminary step that will complement the long-range goal of electronic submission of premarket notifications for food contact substances.

The availability of computerized indexing services such as Med-Line and Tox-line permits requestors to search the scientific literature to determine if a substance has been the subject of toxicity testing that is relevant to the safety of its use as a food contact substance. FDA has also instituted a computerized indexing system (SIREN: Scientific Information Retrieval and Exchange Network) and an image-based document management system (FARM: The Food Additives Regulatory Management System) to permit FDA personnel to easily locate and access data previously submitted to the agency.

4. Duplication and Similar Information Already Available

FDA continues to work with EPA and USDA to eliminate areas of duplicate data collection and evaluation. Within the past two years USDA has eliminated its approval processes for components of food contact materials that duplicated FDA's processes. In addition, The Food Quality Protection Act of 1996, gave sole jurisdiction to EPA for certain substances formerly regulated by FDA as food additives and by EPA as pesticide chemicals. Currently there is no significant duplication of data collection and evaluation for food contact substances among Federal agencies with jurisdiction. In addition, to avoid unnecessary duplication for individual submissions, existing data would be used whenever possible by FDA in evaluating notifications for food contact substances.

Because section 409(h)(4) of the FD&C Act prohibits FDA from disclosing the information in a notification prior to the completion of the Agency's review, such information would not be available to other notifier's until FDA's review is complete. In addition, section 409(h)(2)(C) of the FD&C Act permits only the manufacturer identified in the notification to rely on the notification to legally market the food contact substance. Therefore, the notification process will result in some duplication of review by FDA if a second manufacturer notifies the agency for the same use of the same food contact substance. In order to minimize potential duplication of review, FDA expects to use an image based document management system to permit the agency to track effective notifications and to permit the agency to determine if a food contact substance has already been reviewed by the agency. FDA also expects to maintain a listing of effective notifications available on the agency's internet site.

5. Small Businesses

The premarket notification process for food contact substances may increase the burden on small businesses because small businesses will be required to notify FDA if they wish to manufacture a food contact substance, even if the food contact substance was the subject of a previous notification by another manufacturer. Previously, small businesses would have been able to rely on authorizations requested by other manufacturers under FDA's food additive petition process or threshold of regulation exemption process. Nevertheless, this increased burden will be minimal, because any information presented to support safety of the food contact substance in previous notifications will be available under the Freedom of Information Act (FOIA) after such previous notifications are effective.

FDA has developed guidance documents to assist potential notifiers in preparing notifications. Whenever possible, individual assistance will be given to requesters to minimize the likelihood that unnecessary work is performed. FDA aids small businesses in dealing with the requirements through the Office of Small Manufacturers Assistance and through the scientific and administrative staffs of the agency.

6. Consequences of Less Frequent Information Collection

Failure to provide recommendations for notifications would prevent industry from preparing notifications sufficient to permit new products and would make Federal programs for notification review inefficient. Companies have a right, granted by law, to submit notifications for food contact substances in order to permit marketing of a food contact substance for a new use. Any restriction of this right would decrease the number of new food contact substances that could be legally marketed.

7. Special Circumstances

Data collection for notifications for food contact substances involves no special circumstances and all information would be collected in conformance with the Paperwork Reduction Act.

8. Outside Consultation

In the Federal Register of November 12, 1999 (64 FR 61648), the agency requested comments on the proposed collection of information. One comment was received on FDA's paperwork reduction analysis for the notification program for food contact substances. 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 "PDF" format which 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 Word® and WORDPERFECT® 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 a 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 via 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 causes 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 or 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.

As part of its implementation of the notification process for food contact substances, FDA held a public meeting on March 12, 1999. FDA received comments as a result of the public meeting.

- FDA received comments from industry requesting that the agency permit the submission of notifications in electronic format. FDA is considering these comments in developing specific guidance for the submission of notifications in electronic format. FDA also received comments from industry requesting that the agency respond in writing to the notifier when a notification becomes effective. FDA expects to provide this requested response.

Listed below are persons with whom FDA has consulted to obtain an estimate of the resources needed to prepare a notification for a new use of a food contact substance.

<u>Name</u>	<u>Company</u>	<u>Telephone No.</u>
Banko, Lacy	Eastman Chemical	423-229-1051
Michaels, Mary	BPAmoco	630-836-5742
Misko, George	Keller and Heckman	202-434-4170

Because, the notification process will largely replace the Threshold of Regulation (TOR) process and a large portion of the food additive petition process FDA has also used the most recent

information gathered regarding those information collections. The following are the persons who previously provided information regarding those information collections:

Food Additive Petitions

<u>Name</u>	<u>Firm</u>	<u>Telephone No.</u>
Breder, Charles	Keller and Heckman	202-434-4183
Goldenthal, Edwin	MPI Research	616-668-3336
Graham, Stuart	S.L. Graham	301-249-0295
Harrison, Eliot	Lewis & Harrison	301-652-5495
Heckman, Jerome	Keller and Heckman	202-434-4100
Misko, George	Keller and Heckman	202-434-4170
Olson, William	Center for Regulatory Services	703-620-9175
Schwemmer, Bruce	Bruce EnviroExcel Group	908-689-9215
Takeguchi, Clyde	Phoenix Regulatory Associates	703-406-0906
Wang, Wilhelm	Ciba-Geigy	914-785-4311
Weaver, Jane	Shell Chemical	216-798-6431
Yingling, Gary	McKenna and Cuneo	202-789-7645

Threshold of Regulation Requests

<u>Name</u>	<u>Company</u>	<u>Telephone No.</u>
Banko, Lacy	Eastman Chemical	423-229-1051
Misko, George	Keller and Heckman	202-434-4170
Mary, Michaels	BPAmoco	630-836-5742

9. Payment to Respondents

FDA is not proposing any payment or gift to respondents.

10. Confidentiality of Information

FDA expects that notifications for food contact substances will often contain trade secret and commercial confidential information. Section 409(h)(4) of the FD&C Act prohibits FDA from publicly disclosing information in a notification while it is under review by the Agency. Thereafter, only information that is releasable under the Freedom of Information Regulations (21 CFR Part 20) would be released to the public. This information is also safeguarded by Section 301(j) of the FD&C Act.

A list of effective notifications will be available via the Agency's internet site. This list includes the notifier, the identity of the food contact substance, the effective date of the notification, as well as any appropriate limitations on the use of the food contact substance. It does not include any confidential information.

11. Sensitive Questions

There are no questions of a sensitive nature in the data requirements for notifications for food contact substances.

12. Burden Hours and Explanation

FDA estimates the burden of this information collection as follows:

ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Form	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.101 ² (Category A)	200	FDA 3480	1	200	25	5,000
170.101 ³ (Category B)	55	FDA 3480	2	110	120	13,200
170.101 ⁴ (Category C)	45	FDA 3480	2	90	150	13,500
170.101 ⁵ (Category D)	16	FDA 3480	1	16	150	2,400
Total						34,100

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

² Duplicate notifications for uses of food contact substances.

³ Notifications for uses that would currently be the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.

⁴ Notifications for uses that would currently be the subject of moderately complex food additive petitions.

⁵ Notifications for uses that would currently be the subject of very complex food additive petitions.

FDA expects to receive an average of approximately 416 notifications for new uses of food contact substances per year. FDA bases this estimate of the number of notifications expected annually on the highest number of comparable submission received by the agency in recent years (50 food additive petitions and 54 threshold of regulation exemption requests). FDA also estimated that more notifications will be received annually than petitions and exemption requests because 1) the notification process is proprietary so that each company that wishes to market a food contact substance must separately notify FDA, and 2) the increased predictability of the

notification process is likely to foster innovation and increase the number of food contact substances that may be successfully marketed.

The agency estimated that the likely increase in submissions will be approximately four times the highest recent number of annual submissions for food contact substances (50 food additive petitions (FAP's) and 54 threshold of regulation (TOR) submissions). Thus, FDA estimates that approximately 416 premarket notifications will be submitted annually ($4 \times 50 + 4 \times 54$).

The agency determined the expected number of notifications for four categories of notifications for food contact substances. The burden of the data collection will vary with the type of notification submitted. The following examples represent estimates of information collection for notifications for food contact substances.

Category A: Duplicate notifications for food contact substances. Because this type of notification may reference an earlier agency review, it also requires a minimal amount of time for collection of information: approximately 25 hours per submission to fill out FDA form 3480 (Attachment 3), verify that a previous notification is applicable, and collect the information necessary to establish that a previous notification is applicable. FDA expects approximately 200 notifications of this type will be submitted annually for a total burden of 5,000 hours.

Category B: Notifications for food contact substances that would formerly have been threshold of regulation exemptions and simple indirect additive petitions. Such submissions will require notifiers to perform literature searches and collect available information relevant to the safety of the food contact substance, and in limited instances to perform specific toxicity testing or analytical work to support the safety of such food contact substances. Therefore, FDA expects the burden for collection of information will be minimal: approximately 110 of these notifications will be submitted annually for a total burden of 13,200 hours. In addition, FDA estimates the cost of such testing to be approximately \$12,500 per submission for a total cost of testing of \$1.375M.

Category C: A moderately complex notification consisting of analytical work, 90-day feeding studies, toxicological review of study data, and internal review and the drafting of the notification, requires approximately 150 hours per petition and a total cost for necessary testing of approximately \$350,000. Ninety such notifications are expected to be submitted on an annual basis, resulting in a burden of 13,500 hours and \$31.5M.

Category D: For a notification with complex analytical problems, the estimated time requirement per submission is still approximately 150 hours, but the analytical costs rise slightly to \$375,000. Sixteen such notifications are expected to be submitted on an annual basis, resulting in a burden of 2,400 hours and \$6.0M.

Costs to respondents: Furnishing the information required even in a simple notification for a food contact substance requires a team of professional employees, which may include toxicologists, chemists, environmental scientists, and lawyers. According to information provided by industry trade associations, the collection of information, analytical work, toxicological review and administrative details involved in such a notification (category B) average about 120 hours. Assuming that the aggregate professional hourly cost is \$90, then the cost for submitting such a notification is \$10,800 (calculated by multiplying the hourly cost and the total hours).

13. Annual Cost to Respondents

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

14. Annual cost to Government

The annual costs to the government is \$6.04 million dollars (including salaries and other costs).

15. Explanation of Change in Items 13 and 14

This is a new collection

16. Statistical Analysis, Publication Plans, and Schedule

No comprehensive tabulation of the data is planned or anticipated.

17. Displaying of OMB Expiration Date

The agency is not seeking to not display the expiration date for OMB approval of the information collection.

18. Exceptions to the Certification Statement

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.