

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 or where FDA and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the act requires that a notification include information on the identity and the intended use of the food contact substance and the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) require that a food contact notification (FCN) include FDA Form 3480 entitled "Notification for New Use of a Food Contact Substance" and that a notification for a food contact substance formulation include FDA Form 3479 entitled "Notification for a Food Contact Substance Formulation." These forms will serve to summarize pertinent information in the notification. FDA believes that these forms will facilitate both preparation and review of notifications because the forms will serve to organize information

necessary to support the safety of the use of the food contact substance. 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.

In the **Federal Register** of June 7, 2005 (70 FR 33180), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Form	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.106 ² (Category A)	5	FDA 3479	1	5	2	10
170.101 ^{3,7} (Category B)	5	FDA 3480	1	5	25	125
170.101 ^{4,7} (Category C)	5	FDA 3480	2	10	120	1,200
170.101 ^{5,7} (Category D)	33	FDA 3480	2	66	150	9,900
170.101 ^{6,7} (Category E)	30	FDA 3480	1	30	150	4,500
Total						15,735

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

² Notifications for food contact substance formulations and food contact articles. These notifications require the submission of FDA form 3479 ("Notification for a Food Contact Substance Formulation") only.

³ Duplicate notifications for uses of food contact substances.

⁴ Notifications for uses that are the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.

⁵ Notifications for uses that are the subject of moderately complex food additive petitions.

⁶ Notifications for uses that are the subject of very complex food additive petitions.

⁷ These notifications require the submission of FDA Form 3480.

These estimates are based on FDA's experience with the food contact substances notification system.

- Based on input from industry sources, FDA estimates that the agency will receive approximately five notifications annually for food contact substance formulations.

- FDA also has included five expected duplicate submissions in the second row of table 1 of this document. FDA expects that the burden for preparing these notifications primarily will consist of the manufacturer or supplier filling out FDA Form 3480, verifying that a previous notification is effective, and preparing necessary documentation.

- Based on the submissions received, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information (the third, fourth and fifth rows of table 1 of this document).

- FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources.

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0396]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to

publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal dispute resolution for appeals above the division level.

DATES: Submit written or electronic comments on the collection of information by December 23, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: Under 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(c) 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, including each proposed extension of an existing 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 in this document.

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.

Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level (OMB Control Number 0910-0430)—Extension

This information collection approval request is for an FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding internal agency review of decisions (21 CFR 10.75), dispute resolution during the investigational new drug (IND) process (21 CFR 312.48), and the new drug application/abbreviated new drug application (NDA/ANDA) process (21 CFR 314.103). In addition, the guidance provides information on how the agency will interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the agency, CDER, and CBER. All agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in parts 312 (OMB control number 0910-0014), 314 (OMB control number 0910-0001), and part 601 (21 CFR part 601) (OMB control number 0910-0338), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in

dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(d), 314.50, 314.94, and 601.2) state that information provided to the agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB control number 0910-0014, expires January 31, 2006; and FDA Form 356h, OMB control number 0910-0338, expires August 31, 2005.

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application, and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined, and the guidance recommends, that the following information should be submitted to the appropriate center with each request for dispute resolution so that the center may quickly and efficiently respond to the request: (1) A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (i.e., scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal,

whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The agency suggests submitting the following information with a formal request for dispute resolution: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered

the materials listed previously when identifying the existence of a dispute with the agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

Respondents are expected to be sponsors, applicants, or manufacturers of drug or biological products regulated by the agency under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) who request formal resolution of a scientific or procedural dispute.

Provided below is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately eight sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately one respondent submits requests for formal dispute resolution to CBER annually. The total annual responses are the total number of requests submitted to CDER and CBER

in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 10 requests annually and CBER receives approximately 1 request annually. The hours per response are the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 88 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Requests for Formal Dispute Resolution	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	8	1.25	10	8	80
CBER	1	1	1	8	8
Total					88

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

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0516]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; 2005 Food Safety Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "2005 Food Safety Survey" has been approved by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 24, 2005 (70 FR 29768), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0345. The approval expires on February 30, 2008.

A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0216]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the