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 BURDEN[1]

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

[1]There 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