functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 18, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–1398 Filed 1–25–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0012]

Agency Information Collection Activities; Proposed Collection; Comment Request; Allergen Labeling of Food Products Consumer Preference Survey and Experimental Study on Allergen Labeling of Food Products

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 a voluntary consumer survey entitled ''Allergen Labeling of Food Products Consumer Preference Survey'' and an experimental study entitled ''Experimental Study on Allergen Labeling of Food Products.''

DATES: Submit written or electronic comments on the collection of information by March 28, 2005.

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

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: 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 these topics: (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.

Allergen Labeling of Food Products Consumer Preference Survey

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the Nation's food supply. FDA is planning to conduct a consumer survey about allergen labeling of food products under this authority. The Allergen Labeling of Food Products Consumer Preference Survey will collect information to gauge the impact of certain changes to the food label with respect to information about allergenic ingredients. This data collection is needed to satisfy some of the requirements of the Food Allergen Labeling and Consumer Protection Act (FALCPA) (Public Law 108–282, title II, section 204.4), including the requirement that FDA provide data on consumer preferences in a report to Congress. In particular, section 204.4 of the FALCPA asks FDA to describe in the report ''* * *how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms.'' In addition, the survey will address other issues pertinent to allergen labeling changes mandated by the FALCPA. The data will be collected by means of a pool of people who will be screened (through self-report) for food allergy, and food allergy caregiver status. A balanced sample of 1,000 will be selected. Participation in the survey is voluntary.

FDA estimates the burden of the Allergen Labeling of Food Products Consumer Preference Survey collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	35,000	1	35,000	.0055	193
Pre-test	30	1	30	.167	5

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Survey	1,000	1	1,000	.167	167
Total					365

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

FDA's burden estimate is based on prior experience with consumer surveys very similar to this proposed study.

Experimental Study on Allergen Labeling of Food Products

As previously above, under section 903(b)(2) of the act, FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the Nation's food supply. FDA is planning to conduct an experimental study about allergen labeling of food products under this authority. The Experimental Study on Allergen Labeling of Food Products will collect information to gauge the impact of certain changes to the food label with respect to information about allergenic ingredients. This data collection is needed to satisfy some of the requirements of the FALCPA, including the requirement that FDA provide data on consumer preferences with regard to allergen labeling in a report to Congress. In particular, section 204.4 of the FALCPA asks FDA to describe in the report ''* * *how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms.'' The allergen labeling experiment will supplement data collected by the Allergen Labeling of Food Products Consumer Preference Survey. In addition, the experiment will address other issues pertinent to allergen labeling changes mandated by the FALCPA. The experimental study data will be collected using an Internet panel of approximately 600,000 people who will be screened (through self-report) for food allergy, and food allergy caregiver status. Participation in the allergen experimental study is voluntary.

FDA estimates the burden of the Experimental Study on Allergen Labeling of Food Products collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	600,000	1	600,000	.0028	1,680
Pre-test	30	1	30	.167	5
Experiment	9,000	1	9,000	.167	1,503
Total					3,188

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

FDA's burden estimate is based on prior experience with internet panel experiments similar to the study proposed here.

Dated: January 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1395 Filed 1–25–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

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 Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 25, 2005.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.