VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: May 4, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–9273 Filed 5–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0012]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 June 9, 2005.

ADDRESSES: 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: Peggy Robbins, Office of Management Programs (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.

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 (see table 1 of this document) 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.

Experimental Study on Allergen Labeling of Food Products

As previously stated, 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 (see table 2 of this document) 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 people who will be screened (through self-report) for food allergy, and food allergy caregiver status. Participation in the allergen experimental study is voluntary.

In the **Federal Register** of January 26, 2005 (70 FR 3711), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received two comments, both from the same consortium of food allergy interested organizations: The American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and The Food Allergy & Anaphylaxis Network (FAAN). The comments were identical and are addressed in the following paragraphs.

The comments applauded FDA's goals for the research. The comments suggested that to improve the quality of the study and analysis, the agency should do the following: (1) Consider using FAAN's membership rolls to draw the samples, (2) screen the sampling frame to maximize the likelihood of recruiting truly food allergic individuals, (3) acknowledge that some households have multiple individuals who are food allergic, (4) recognize that some individuals do not have Internet access, (5) consider using advisory labeling that is currently found in the marketplace, and (6) collaborate closely with appropriate representatives from their organizations.

The agency has considered the offer to use FAAN's membership rolls to draw the study samples and has determined that the high likelihood of bias would render results not generalizable. The agency does not agree that using FAAN's membership rolls will yield a better sample than can be acquired by using established Internet panels.

FDA will utilize two consumer Internet panels to collect data for this research. One of the advantages to using Internet panels is the small ratio between the cost of the research and the

quality of the data collected. Another advantage is the minimal amount of field time needed to collect the information. This is an important consideration because of the FALCPA requirements for providing the informational report to Congress. A potential disadvantage of using Internet panels for data collection is the risk that the Internet panels' constituency may not adequately represent the general population, lessening its potential to provide generalizable data. A description of each panel follows.

The Allergen Labeling of Food Products Consumer Preference Survey will utilize Knowledge Network's (a private research firm) Web-enabled panel. Knowledge Network's panel consists of 40,000 households who have agreed to participate in research studies conducted through the Internet. Knowledge Network's Web-enabled panel was constructed using random digit dialing procedures rendering samples drawn from them generalizable to the general population. Both Internet and Noninternet users were recruited. Both groups received equipment that allows them to participate in research via the Internet.

The sample for the Experimental Study on Allergen Labeling of Food Products is Synovate, Inc.'s (a private research firm) Internet panel. Synovate's panel consists of 500,000 households who have agreed to participate in research studies conducted through the Internet. This panel was not constructed using random digit dialing procedures but rather by recruiting through multiple media. The panel was designed to closely match the general population on major demographic characteristics.

The agency agrees that it is important to implement rigorous screening requirements in order to obtain samples of truly food allergic individuals. Many people believe that they have a food allergy when, in fact, they have an intolerance to a particular food or they have celiac disease. While these two conditions can produce symptoms that are similar to those sometimes seen with food allergies, the physiological mechanisms producing the reactions are entirely different. The agency has designed a screener that all panel members will receive in which they would be asked first whether or not they have a food allergy or if they regularly prepare food for someone with a food allergy, and then whether or not they have been medically diagnosed as food allergic. Then they are asked to state which diagnosis method was used.

The agency agrees that some households have multiple members who are food allergic. As described previously in the discussion on the screener, Internet panel members are asked whether or not they, or someone for whom they regularly prepare food, has a food allergy. The reason we made the ''prepare food for someone with a food allergy'' distinction is to be able to categorize the respondent as a caregiver to someone with a food allergy. It is important to point out that the study will also recruit individuals who do not meet the criteria for food-allergic individual or caregiver. The nonfood allergic group will be analyzed separately from the food allergic group.

The agency believes it is important to acknowledge that the population of food allergic individuals is not static and that at any time someone can become a member. These individuals must be able to immediately use the food label to determine whether or not it is safe for them to consume the food.

The agency agrees that some individuals do not have access to the Internet. As discussed in the previous paragraphs, the Internet panel that will be used to draw the survey sample was constructed using random digit dialing procedures, and those without Internet access were supplied with equipment which allows them to access the Internet and to participate in consumer research.

The agency agrees that it is important to use advisory labeling that is currently found in the marketplace. The agency has used the FAAN list of advisory statements and another list created by an informal market survey, and has classified the statements into groupings of similar statements. The statements that appear most often in each of the groupings were chosen for analysis in the study.

The agency agrees that for the research to be of the highest quality and utility, collaboration with appropriate representatives from AAAAI, ACAAI, and FAAN is important and has already implemented this collaboration.

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]

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	500,000	1	500,000	0.0055	2,750
Pretest	30	1	30	0.167	5
Survey	1,000	1	1,000	0.167	167
Total					2,922

[1]There are no capital costs or operating and 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.

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]

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	40,000	1	40,000	0.0055	220

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	30	1	30	0.167	5
Experiment	4,000	1	4,000	0.167	668
Total					893

[1]There are no capital costs or operating and 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: May 4, 2005.

Jeffery Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9328 Filed 5–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Neurological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 17, 2005, from 8:30 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512513. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will also hear an update on the status of recent devices brought before the committee. Subsequently, the committee will discuss, make recommendations, and vote on a premarket approval application for a selective head cooling system intended for use in infants 36 weeks of gestation or older at risk for moderate to severe hypoxic-ischemic encephalopathy (HIE) to prevent or reduce the severity of HIE. Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 3, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by June 3, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at 240–276–0450, ext. 113 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 3, 2005.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

[FR Doc. 05–9296 Filed 5–9–05; 8:45am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 13 and 14, 2005, from 8 a.m. to 5:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Teresa A. Watkins, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: *watkinst@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512545. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 13, 2005, the committee will discuss the implications