relating health care choices with individual beliefs may help guide these educational efforts. The intent of this survey is to understand the role personal responsibility plays when people with Medicare make health care decisions; *Affected Public:* Individuals or Households; *Number of Respondents:* 1580; *Total Annual Responses:* 1580; *Total Annual Hours:* 300.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra/,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice to the address below: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Melissa Musotto, PRA Analyst, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 10, 2005.

Jimmy Wickliffe,

Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 05–11931 Filed 6–16–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Follow-up to the National Survey of Child and Adolescent Well-Being.

OMB No.: 0970–0202.

Description: The Department of Health and Human Services intends to collect data on a subset of children and families who have participated in the National Survey of Child and Adolescent Well-Being (NSCAW). The NSCAW was authorized under Section 429 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. The survey began in November 1999 with a national sample of 5,501 children ages 0–14 who had been the subject of investigation by Child Protective Services (CPS) during the baseline data collection period, which extended from November 1999 through April 2000. Direct assessments and interviews were conducted with the children themselves, their primary caregivers, their caseworkers, and, for school-aged children, their teachers.

Follow-up data collections were conducted 12 months, 18 months and 36 months post-baseline. The current data collection plan involves only a subset of 1,497 children from the original sample, that is, children who were ages 0–12 months during the baseline period. The original sample design for NSCAW was stratified to include an over-sample of infants; thus, the subset that is the subject of this data collection is a representative sample of infants who were the targets of CPS investigations during the survey's baseline data collection period. This group will be at the beginning of their formal schooling as the next data collection begins, and will allow for the identification of early risk and protective factors, as well as the influence of services and service systems, on their functioning as they enter this critical transition period.

The NSCAW is unique in that it is the only source of nationally representative, firsthand information about the functioning and well-being, service needs and service utilization of children and families who come to the attention of the child welfare system. Information is collected about children's cognitive, social, emotional, behavioral and adaptive functioning, as well as family and community factors that are likely to influence their functioning. Family service needs and service utilization also are addressed in the data collection. The data collection for the follow-up will follow the same format as that used in previous rounds of data collection, and will employ the same instruments that have been used with 5- to 7-year-olds in previous rounds. Data from NSCAW are made available to the research community through licensing arrangements from the National Data Archive on Child Abuse and Neglect, housed at Cornell University.

Respondents: Children, who are clients of the child welfare system, their primary caregivers, caseworkers, and teachers.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Child Interview	1,017	1	1.10	1,119
Caregiver Interview	1,017	1	1.40	1,424
Caseworker Interview	299	1	.75	224
Teacher Questionnaire	790	1	.75	592
Salivary cortisol collection	299	1	1.25	374

Estimated Total Annual Burden Hours: 3,733.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promnade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eo.gov*.

Dated: June 13, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–11969 Filed 6–16–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0231]

Draft Report of the Threshold Working Group, Center for Food Safety and Applied Nutrition: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food; Availability; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft report entitled ''Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food.'' The draft report was prepared by an interdisciplinary group of scientists from FDA's Center for Food Safety and Applied Nutrition (CFSAN). This report was prepared to facilitate the further development of CFSAN's policy for food allergens, including the center's implementation of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

DATES: Submit comments and scientific data and information by August 16, 2005.

ADDRESSES: Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and scientific data and information to *http://www.fda.gov/dockets/ecomments*.

Submit written requests for single copies of the draft report to Sherri Dennis, Center for Food Safety and Applied Nutrition (see **FOR FURTHER INFORMATION CONTACT**). Send one self-adhesive label with your address to assist that office in processing your request. You also may request a copy of the draft report by faxing your name and mailing address with the name of the document you are requesting to the CFSAN Outreach and Information Center at 1–877–366–3322. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Center for Food Safety and Applied Nutrition (HFS–06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1903.

SUPPLEMENTARY INFORMATION:

I. Background

Food allergies are estimated to affect approximately six percent of infants and children and four percent of adults in the United States. A food allergy is an idiosyncratic response of the immune system to naturally occurring proteins in a food. The most severe and immediately life-threatening food allergic responses are associated with immunoglobulin E (IgE) mediated hypersensitivity. In this country, eight foods or food groups—peanuts, soybeans, cow's milk, eggs, fish, crustacean shellfish, tree nuts, and wheat—account for 90 percent of food allergies.

Food allergic reactions vary in severity, ranging from mild symptoms (such as skin or eye irritation) to severe, life-threatening responses (such as anaphylaxis or systemic shock.) The amount of protein needed to provoke an allergic response varies. Factors that affect the severity of an allergic response include the food from which the protein is derived, the nature of the processing of the food, the food matrix containing the allergenic protein, and the sensitivity of the individual. There is a general consensus that, for most food allergic individuals, exposure to protein below a certain level is unlikely to elicit an allergic response. Although it has not been clearly defined, the term ''threshold'' has frequently been used to describe the lowest level of protein from an allergenic food that will elicit a response in a sensitive individual.

There is currently no known cure for food allergies. Accordingly, strict avoidance of the offending food or foods at levels that will elicit an adverse effect is the only means to prevent potentially serious reactions. Thus, food allergic consumers need accurate, complete, and informative labels on food to protect themselves.

In August 2004, Congress enacted the FALCPA (Public Law 108–282), which amends the Federal Food, Drug, and Cosmetic Act (the act), and requires that the label of a food product that is or contains an ingredient that bears or contains a ''major food allergen'' declare the presence of the allergen as specified by FALCPA. FALCPA defines ''major food allergen'' as one of eight foods or a food ingredient that contains protein derived from one of those foods. FALCPA provides two processes by which an ingredient may be exempted from the FALCPA labeling requirements—a petition process (section 403 of the act (21 U.S.C. 343(w)(6)) and a notification process (21 U.S.C. 343(w)(7)). Under the petition process, an ingredient may be exempt if the petitioner demonstrates that the ingredient ''does not cause an allergic reaction that poses a risk to human health.'' Under the notification process, an ingredient may be exempt if the notification contains scientific evidence that demonstrates that the ingredient ''does not contain allergenic protein,'' or if FDA previously has determined, under section 409 of the act (21 U.S.C. 348), that the food ingredient does not cause an allergic response that poses a risk to human health. Understanding food allergen thresholds and developing a sound analytical framework for such thresholds are likely to be centrally important to FDA's analysis of, and response to, FALCPA petitions and notifications.

FALCPA also requires FDA to define and permit the use of the term ''gluten free.'' Such labeling is important to patients suffering from celiac disease, an immune-mediated illness. Strict avoidance of gluten at levels that will elicit an adverse effect is the only means to prevent potentially serious reactions. Thus, consumers susceptible to celiac disease need accurate, complete, and informative labels on food to protect themselves. Understanding thresholds for gluten will help FDA develop a definition of ''gluten free'' and identify appropriate use of the term.

Section 204 of FALCPA directs FDA to prepare and submit a report to Congress. The report will focus principally on the issue of cross-contact of foods with food allergens, and will describe the types, current use of, and consumer preferences with respect to advisory labeling. Cross-contact may occur as part of the food production process where residues of an allergenic food are present in the manufacturing environment and are unintentionally incorporated into a food that is not intended to contain the food allergen, and thus, the allergen is not declared as an ingredient on the food's label. In some cases, the possible presence of the food allergen is declared by a voluntary advisory statement. Understanding food allergen thresholds and developing a sound analytical framework for such thresholds is also likely to be useful in addressing food allergen cross-contact and the use of advisory labeling.

Both as part of its ongoing risk management of food allergens and in response to FALCPA, CFSAN established an internal, interdisciplinary group (the Threshold Working Group). The Threshold Working Group was established to evaluate the current state of scientific knowledge regarding food allergies and celiac disease, to consider various approaches to establishing thresholds

for food allergens and for gluten, and to identify the biological concepts and data needed to evaluate the scientific soundness of each approach. The draft report entitled ''Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food'' is the result of the working group's deliberations.

In the **Federal Register** of May 23, 2005 (70 FR 29528), FDA announced a meeting of the agency's Food Advisory Committee (FAC) on July 13, 14, and 15, 2005. At this meeting, the FAC will be asked to evaluate the draft report entitled ''Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food.'' In particular, the FAC will advise FDA whether, in the committee's view, the draft report is scientifically sound in its analyses and approaches and adequately considers available relevant data on food allergens and on gluten. In seeking the committee's advice, FDA plans to pose a series of scientific questions. These questions will be posted on CFSAN's Web site at *http://www.cfsan.fda.gov/~lrd/vidtel.html* on July 12, 2005. Members of the public who may wish to participate in the FAC meeting, by written submission or an oral presentation, should consult the meeting notice for information regarding such participation.

In addition to the FAC proceedings, the agency believes it would be useful to receive public comments on the Threshold Working Group's draft report. The draft report describes a number of areas in which the working group concluded that the body of scientific data relating to food allergen thresholds is incomplete. Accordingly, FDA requests that members of the public submit comments and any relevant scientific data and information, particularly data and information that can fill the data gaps identified in the draft report.

II. Request for Comments and for Scientific Data and Information

Interested persons should submit comments and scientific data and information to the Division of Dockets Management (see **ADDRESSES**). Three copies of all comments and scientific data and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

III. Electronic Access

The draft report is available electronically at *http://www.cfsan.fda.gov/~dms/wh-alrgy.html*.

Dated: June 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12041 Filed 6–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Empahsis Panel; Emerging Technologies for Cancer Research.

Date: July 14–15, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Joyce C. Pegues, PhD; Scientific Review Administrator; Special Review Administrator; Special Review and Logistics Branch; Division of Extramural Activities; National Cancer Institute; 6116 Executive Blvd. 7149; Bethesda, MD 20892. 301/594–1286. *peguesj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 10, 2005.

LaVerne Y. Springfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11987 Filed 6–16–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Review of Training Applications (T32s).

Date: July 11, 2005.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Columbia Hotel, 10207 Wincopin Circle, Columbia, MD 21004.

Contact Person: Charles Joyce, PhD, Review Branch, NHLBI, National Institutes of Health, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, (301) 435–0288.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Myelodysplastic Syndrome (MDS): Seeking cure through discovery on pathogenesis and disease progression.

Date: July 12–13, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Columbia Hotel, 10207 Wincopin Circle, Columbia, MD 21004.

Contact Person: Katherine M. Malinda, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7198, Bethesda, MD 20892, (301) 435–0297

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Cellular and Genetic Discovery Toward Curative Therapy in Myeloproliferative Disorders (MPD)

Date: July 13, 2005.

Time: 8 a.m. to 5 p.m.