DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic 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: Dermatologic and Ophthalmic 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 November 4, 2002, from 8:30 a.m. to 5:30 p.m. and November 5, 2002, from 8 a.m. to 1 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both the days, committee will make recommendations for the development of a proposed draft guidance concerning the development of products for mild to moderate acne vulgaris. Issues to be considered include: (1) The evidence for effectiveness; (2) appropriate outcome measures and their analyses; (3) possible acceptable indications such as inflammatory, noninflammatory or just mild to moderate acne vulgaris; and (4) means for conveying evidence for effectiveness in the label to enhance its usefulness for clinicians and patients. Time will be included in the agenda for the pharmaceutical industry to present their views on the development of the draft guidance. Please register to present (see *Contact Person*) by October 18, 2002.

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 October 18, 2002. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. on November 4, 2002, and between approximately 8:15 a.m. and 8:45 a.m. on November 5, 2002. Time allotted for each presentation may be limited. If you wish to make a brief statement during the open public hearing, please contact the Executive Secretary (see Contact Person), by October 18, 2002.

You will be asked to submit a brief summary of your planned statement and provide information on how we may contact you before the meeting.

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 Karen Templeton-Somers 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: October 9, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–26330 Filed 10–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Infant Formula Subcommittee of the Food 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: Infant Formula Subcommittee of the Food Advisory Committee.

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

Date and Time: The meeting will be held on November 18, 2002, from 8 a.m. to 6 p.m. and November 19, 2002, from 8 a.m. to 5 p.m.

Location: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Conference Center, 4700 River Rd., Riverdale, MD, 301–734–8010.

Contact Person: Jeanne E. Latham, Center for Food Safety and Applied Nutrition (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1756, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The meeting's purpose is to discuss the scientific issues and principles involved in assessing and evaluating whether a ''new'' infant formula supports normal physical growth in infants when consumed as a sole source of nutrition. This is the second meeting of a series of advisory committee meetings to discuss the scientific issues involved in evaluating whether a new infant formula supports normal physical growth.

FDA will post information relating to this meeting on the Internet at *http://www.cfsan.fda.gov/~lrd/vidtel.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 November 1, 2002. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on November 19, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 13, 2002, 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 Jeanne E. Latham 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: October 9, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–26325 Filed 10–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Electroencephalogram and Event-Related Potential Intermediate Phenotypes for Alcoholism in a Low Prevalence American Indian Tribe

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, regarding the opportunity for public comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection Title: Electroencephalogram (EEG) and Event-Related Potential (ERP) intermediate phenotypes for alcoholism in a low prevalence American Indian tribe. Type of Information Collection Request: New. Need and Use of Information Collection: An extensive data set has already been collected by the Laboratory of Neurogenetics, NIAAA, on 294 members of a Southeastern American Indian tribe. We propose to re-contact these individuals to collect additional information. Approximately 100 of the original participants were originally selected as a representative sample of the population. The remaining 194 individuals are family members of alcoholic probands from the population sample. We propose to expand the study to collect (a) measures of intermediate phenotypes for alcoholism and (b) survey-based selected personality characteristics from the same tribal members. Intermediate phenotypes are biological traits that may be influenced by variation at fewer genes and may mediate different aspects of the disease. The intermediate phenotype measurements that we will collect include resting EEG phenotypes (low voltage alpha (LVA) and beta spectral power), ERPs and heart rate variability (HRV). LVA has been found to be more abundant in alcoholics with co-morbid anxiety disorders. Increased beta power has been associated with increased risk of relapse. P300 ERP amplitude is reduced in alcoholics and their alcohol-naïve children. HRV is a potential intermediate phenotype for alcoholism and major depression. We also propose to administer the Temperament and Character Inventory, a standard, survey-based measure of harm avoidance, novelty seeking, reward dependence, and persistence. The use of such intermediate phenotypes and personality measures is likely to increase our ability to find vulnerability genes for alcoholism. We will use these EEG and EKG intermediate phenotypes and personality dimensions in (1) candidate gene analyses and (2) linkage analyses, utilizing the existing DNA, in order to determine the genes that increase an individual's risk for alcoholism and anxiety disorders.

The re-recruitment of the original study participants will start in spring 2003. The study is expected to run for 6 months. Frequency of response: Once per respondent. Affected Public: Individuals. Type of Respondents: Adult members of the Southeastern American Indian tribe who were participants in the original study.

The reporting burden is as follows: Estimated Number of Respondents: It is estimated, after a survey by tribal members, that we will be able to re-recruit approximately 280 of the 294 original participants. Estimated Number of Responses per Respondent" One response per respondent. Average Burden Hours per Response: Three hours per individual, for a total respondent burden of 840 hours. Estimated Total Annual Burden Hours Requested: 840 hours. There are no Costs to Respondents to report. There are no Capital Costs to report. There are no Operating or Maintenance costs to report.

Request for Comments: Written comments and suggestions from the public and affected agencies are invited on the following points: (1) Whether the data collection is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Mary-Anne Enoch M.D., NIH/NIAAA/DICBR/LNG, 12420 Parklawn Drive, Park 5 Building, Room 451, MSC 8110, Bethesda, MD 20892–8110, or e-mail your request to: *maenoch@niaaa.nih.gov.* Dr. Enoch can be contacted by telephone at 301–496–2727.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 7, 2002.

Stephen Long,

Executive Officer, NIAAA.

[FR Doc. 02–26212 Filed 10–15–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 5, 2002, page 50679–50680 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants. *Type of Information Collection Request:* EXTENSION, OMB No. 0925–0496, expiration date 10–31–2002. *Need and Use of Information Collection:* The Mayo Lung Project (MLP) was an NCI-funded randomized controlled trial (RCT) of lung cancer screening