includes adequate data demonstrating that ecamsule has been marketed for a material time and to a material extent as required by § 330.14 (21 CFR 330.14) (Ref. 2). Ecamsule-containing sunscreen products have been marketed directly to consumers for over 5 continuous years in 48 countries, with an estimated 472 million dosage units marketed in 55 countries. Therefore, ecamsule, in concentrations of up to 10 percent, is eligible for inclusion in the OTC sunscreen drug monograph as a single active ingredient and in combination with GRASE sunscreen active ingredients found in § 352.10.

II. Request for Data and Information

FDA invites all interested persons to submit data and information on the safety and effectiveness of this single active ingredient in order for us to determine whether it is GRASE and not misbranded under recommended conditions of OTC use (see § 330.14(f)). FDA is also seeking data to establish the safety and effectiveness of ecamsule for use as a sunscreen active ingredient when combined with GRASE sunscreen active ingredients found in § 352.10. The effectiveness data should include studies conducted according to the testing procedures in the sunscreen monograph (i.e., part 352, subpart D). Such data for combinations should meet both criteria described in the sunscreen monograph (§ 352.20):

- The ingredient contributes a Sun Protection Factor (SPF) of at least 2 to the final formulation;
- The SPF of the final formulation equals at least two times the number of active ingredients

The safety data should include animal and human studies that meet current scientific standards (see § 330.14(f)(1) and 21 CFR 330.10(a)(2)).

III. Marketing Policy

Under § 330.14(h), any product containing the condition for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA for Ecamsule (Terephthalylidene Dicamphor Sulfonic Acid) Submitted by L'Oreal USA Products, Inc., dated September 18, 2007.

2. FDA's evaluation of the TEA for ecamsule.

Dated: September 4, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21291 Filed 9–11–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Proposed Collection; Comment Request; Health Behaviors in School-Age Children

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

Proposed Collection

Title: Health Behaviors in School-Age Children—United States.

Type of Information Collection Request: Extension OMB control number 0925–0557, expiration date 01/31/09.

Need and Use of Information Collection: The goal of this research is to obtain data from a survey of adolescent health behavior conducted in the United States with a national probability sample of adolescents. This information will enable the improvement of health services and programs for youth. The study should provide needed information about adolescents nationally and will also enable international comparisons.

This U.S. survey is linked to the broader Health Behaviors in School-Age Children (HBSC) study, in which surveys are conducted every four years among nationally representative samples of students at ages 11, 13, and 15 years of age in about 40 countries. The HBSC was conducted in the U.S. previously in 1997/1998, 2001/2002 and 2005/2006. Previous HBSC–U.S. surveys showed that U.S. 15-year-old youth are less likely to smoke than students in most other countries surveyed, even though 11-year-old U.S. students experiment with tobacco at higher rates than youth in other countries. The most recent survey demonstrated that U.S. youth are more likely to be overweight and obese than students in the other HBSC countries and more likely to be dieting to lose weight. U.S. eating habits were also shown to be somewhat less healthful than in other countries, with a comparatively high proportion of youth consuming sugar-sweetened soft drinks and among the lowest proportions of youth eating breakfast. The 2009/2010 U.S. survey will address a sample of health-related factors according to rigorous research protocols developed by the HBSC. The international HBSC survey requires at least 1,536 youth in each age group (ages 11, 13, and 15) and a total of 5,000 students. In the U.S., a nationally representative sample of children in grades 6 through 10 will be surveyed and minority children will be over-sampled to permit comparisons across under-represented populations. The children will be students from approximately 420 schools; in order to assess health programs in those schools and how the school environment supports health behaviors, a school administrator and the lead health education teacher from each school will be surveyed.

Affected Public: School-age children.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adolescents	14,672	1	0.75	11,004
School Administrators	386	1	0.33	127

The estimated annualized cost to respondents is $5,392. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information 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 used; (3) 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 Dr. Ronald Iannotti, Prevention Research Branch, Division of Epidemiology, Statistics, and Prevention Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Building 6100, 7B05, 9000 Rockville Pike, Bethesda, Maryland, 20892–7510, or call non-toll free number (301) 435–6951 or E-mail your request, including your address to *ri25j@nih.gov.*

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: September 3, 2008.

Paul L. Johnson,

Project Clearance Liaison, NICHD, National Institutes of Health.

[FR Doc. E8–21327 Filed 9–11–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cellular Signaling and Regulatory Systems Study Section, October 2, 2008, 8 a.m. to October 3, 2008, 5 p.m., Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007 which was published in the **Federal Register** on August 18, 2008, 73 FR 48219–48220.

The meeting will be held one day only October 2, 2008. The meeting time and location remain the same. The meeting is closed to the public.

Dated: September 3, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–21036 Filed 9–11–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 paten table 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: Immunology Integrated Review Group, Hypersensitivity, Autoimmune, and Immune-mediated Diseases, Study Section.

Date: October 2–3, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Bahiru Gametchu, DVM, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301–435–1225, *gametchb@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated, Review Group Clinical Neuroplasticity and Neurotransmitters Study Section.

Date: October 2–3, 2008.

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

Agenda: To review and evaluate grant applications

Place: Holiday Inn, San Franscisco-Fisherman's Wharf, 1300 Columbus Avenue, San Francisco, CA 94133.

Contact Person: Suzan Nadi, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301–435–1259, *nadis@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Clinical Neuroscience and Neurodegeneration.

Date: October 6, 2008.

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

Agenda: To review and evaluate grant applications.

Place: DoubleTree Hotel Washington, DC, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

Contact Person: Seetha Bhagavan, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 435–1121, *bhagavas@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group Acute Neural Injury and Epilepsy Study Section.

Date: October 6–7, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Adagio, 550 Geary Street, San Francisco, CA 94102.

Contact Person: Seetha Bhagavan, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 435–1121, *bhagavas@csr.nih.gov*.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group Instrumentation and Systems Development Study Section.

Date: October 8, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Carlyle Suites, 1731 New Hampshire Avenue, NW., Washington, DC 20009.

Contact Person: Marc Rigas, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7849, Bethesda, MD 20892, 301–402–1074, *rigasm@mail.nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group Skeletal Muscle and Exercise Physiology Study Section.

Date: October 9, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Willam F. Bolger Center, 9600 Newbridge Drive, Main, Potomac, MD 20854.

Contact Person: Richard J. Bartlett, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7814, Bethesda, MD 20892, 301–435–6809, *bartletr@csr.nih.gov*.

Name of Committee: Oncological Sciences Integrated Review Group, Drug Discovery and Molecular Pharmacology Study Section.

Date: October 13–14, 2008.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: Hungyi Shau, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214,