Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments or information to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Domini Cassis, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–2342, e-mail: *domini.cassis@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 24, 2008 (73 FR 15530), FDA published a notice of a meeting for the Ophthalmic Devices Panel of the Medical Devices Advisory Committee (the panel). At the meeting on April 25, 2008, the panel was asked to consider general issues concerning the post market experience with laser-assisted *in situ* keratomileusis (LASIK) procedures. Interested persons were invited to present data, information, or views, orally or in writing, to the panel regarding these topics. At the conclusion of the meeting, FDA requested that interested persons provide input on LASIK, including comments regarding tools the agency uses to improve patient safety, such as patient labeling, information on FDA's LASIK Web site, and other outreach initiatives.

Using information gathered at the April 25, 2008, panel meeting, the agency has updated information contained on its LASIK Web site, has strengthened its post market surveillance activities, and is now seeking ways to better understand quality of life issues following LASIK procedures that may relate to safety and effectiveness of LASIK devices. At this time, the agency is interested in receiving public comments regarding the post market experience associated with the use of LASIK, as well as information regarding potential barriers that may exist in providing the agency with feedback regarding LASIK procedures. Information and comments submitted to the docket will assist us in identifying ways in which we can improve our public outreach efforts regarding the safety and effectiveness of LASIK devices.

II. Submission of Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. All comments submitted to the public docket are public information and may be posted to the FDA's Web site at *http://www.fda.gov* for public viewing. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA only through the FDMS at *http://www.regulations.gov*.

Dated: September 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21339 Filed 9–11–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0474]

Ecamsule Eligibility for Inclusion in Monograph; Over-the-Counter Sunscreen Drug Products for Human Use; Request for Safety and Effectiveness Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration is announcing a call-for-data for safety and effectiveness information on the following condition as part of FDA's ongoing review of over-the-counter (OTC) drug products: Ecamsule (terephthalylidene dicamphor sulfonic acid), in concentrations of up to 10 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients that are generally recognized as safe and effective (GRASE) and are found in the sunscreen monograph regulations. FDA reviewed a time and extent application (TEA) for ecamsule and determined that it is eligible for consideration in our OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether ecamsule can be generally recognized as safe and effective (GRASE) for its proposed OTC use.

DATES: Submit data, information, and general comments by December 11, 2008.

ADDRESSES: You may submit comments, identified by docket number FDA–2008–N–0474, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (For paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, we are no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael L. Chasey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MS 5411, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Eligibility of Ecamsule

In September 2007, FDA received a TEA (Ref. 1) requesting that ecamsule be eligible for review under our OTC sunscreen drug monograph (part 352 (21 CFR part 352)). After reviewing the TEA, the agency believes that it

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.