

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 [*insert date 90 days after date of publication in the Federal Register*].

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

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FDA-2008-N-0474

NRD

DDM
Display Date 9-11-08
Publication Date 9-12-08
Certifier D. Hawkins

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

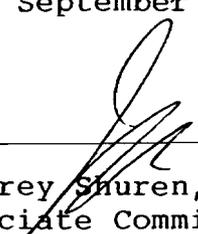
Under § 330.14(h), any product containing the condition for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

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: 9/4/08
September 4, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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Dawn P. Hawkins