

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7-1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 25, 2010.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. 2010-13145 Filed 6-1-10; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2003-N-0196] (formerly Docket No. 2003N-0233)

Drometrizole Trisiloxane Eligibility for Potential Inclusion in Sunscreen Monograph; Over-the-Counter Sunscreen Drug Products for Human Use; Request for Safety, Effectiveness, and Environmental Data

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: As part of our ongoing review of over-the-counter (OTC) drug products, we (Food and Drug Administration, FDA) are announcing a call-for-data for safety, effectiveness, and environmental information for drometrizole trisiloxane, in concentrations up to 15 percent, as a sunscreen single active ingredient and in combination with generally recognized as safe and effective (GRASE) sunscreen active ingredients found in the sunscreen monograph. We reviewed a time and extent application (TEA) for drometrizole trisiloxane and determined that it is eligible to be considered for inclusion in our OTC drug monograph system. We will evaluate the submitted safety and effectiveness data and information to determine whether drometrizole trisiloxane can be GRASE for its proposed OTC use. We also request data and information to assess the projected environmental effects of a potential GRASE determination in order to assist us in complying with the requirements of the National Environmental Policy Act of 1969 (NEPA).

DATES: Submit data, information, and general comments by August 31, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2003-N-0196, 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.

Instructions: All submissions received must include the agency name and docket number. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, 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:

Anita Kumar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5445, Silver Spring, MD 20993, 301-796-2090.

SUPPLEMENTARY INFORMATION:

I. Eligibility of Drometrizole Trisiloxane

In January 2009, we received a TEA (Ref. 1) requesting that drometrizole trisiloxane be found eligible for review and potential inclusion in our OTC sunscreen drug monograph (part 352 (21 CFR part 352)). After reviewing the TEA, we believe that it includes adequate data demonstrating that drometrizole trisiloxane has been marketed for the prevention of sunburn for a material time and to a material extent as required by § 330.14 (21 CFR 330.14) (Ref. 2). Drometrizole trisiloxane-containing sunscreen products indicated for the prevention of sunburn have been marketed directly to consumers for over 5 continuous years in 40 countries, with over 177 million dosage units marketed in 54 countries. Therefore, we conclude that drometrizole trisiloxane, in concentrations up to 15 percent, is eligible to be considered for potential 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

We invite all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of drometrizole trisiloxane for use as an active ingredient in OTC sunscreen products. The data should be sufficient so that we can determine whether the ingredient can be GRASE and not misbranded under recommended conditions of OTC use. Interested parties may refer to 21 CFR 330.10(a)(4) regarding the evidence necessary for establishing general recognition of safety and effectiveness.

Because the TEA that we reviewed did not include an official or proposed United States Pharmacopeia-National Formulary (USP-NF) drug monograph for drometrizole trisiloxane, we are asking interested parties to provide such a monograph to us. An active ingredient must be recognized in an official USP-NF drug monograph that sets forth its standards of identity, strength, quality, and purity in order to be included in a final OTC monograph (§ 330.14(i)).

In addition, as stated in 21 CFR 25.1, FDA regulations must comply with NEPA. To comply with NEPA, an environmental assessment (EA) of agency actions is required unless we determine that a categorical exclusion is warranted. Therefore, we also invite all interested persons to either submit data and information that would support a determination that the potential inclusion of drometrizole trisiloxane in the OTC monograph for sunscreen meets the requirements for any categorical exclusion found in 21 CFR 25.31, or to prepare an EA, if necessary. For additional information on the types of information that would support our environmental assessment, please refer to section IV (pages 9 through 27) of the Center for Drug Evaluation and Research Guidance on Environmental Assessment of Human Drug and Biologic Applications. The guidance document can be viewed at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070561.pdf>.

For all data and information submitted, we request that a submitter segregate any data or information that the submitter believes is protected from disclosure by 5 U.S.C. 552(b), 18 U.S.C. 1905, or 21 U.S.C. 331(j) or 360(j)(c). If such data or information is included in the submission, we request that the submitter summarize the confidential information, to the extent possible, so that the summary can be publicly disclosed (see 21 CFR 25.50 and 25.51(a); § 330.14(f)).

III. Marketing Policy

Under § 330.14(h), any sunscreen product containing drometrizole trisiloxane 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**) under Docket No. FDA-2003-N-0196 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Redacted TEA for drometrizole trisiloxane submitted by L'Oreal USA Products, Inc., dated January 21, 2009.

2. FDA's evaluation of the TEA for drometrizole trisiloxane.

Dated: May 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-13001 Filed 6-1-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Cardiovascular and Renal 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: Cardiovascular and Renal 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 July 28, 2010, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College, 3501 University Blvd. East, Adelphi, MD. The conference center telephone number is 301-985-7300.

Contact Person: Elaine Ferguson, c/o Christine Shipe, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2419, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8532, e-mail:

elaine.ferguson@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 28, 2010, the committee will discuss new drug application (NDA) 22-433, ticagrelor tablets, 90 milligrams, manufactured by AstraZeneca LP, for the proposed indication for use in acute coronary syndrome (including heart attacks and any of a group of signs and symptoms, such as chest pain or shortness of breath, that are consistent with blockages in the blood vessels that supply the heart).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

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 on or before July 14, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before July 6, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public

hearing session. The contact person will notify interested persons regarding their request to speak by July 7, 2010.

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 Elaine Ferguson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 27, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-13141 Filed 6-1-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; CMS Computer Match No. 2010-03, HHS Computer Match No. 1003, SSA Computer Match No. 1048, IRS Project No. 241

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of renewal of an existing computer matching program (CMP) that has an expiration date of June 30, 2010.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the renewal of an existing CMP between CMS, the Internal Revenue Service (IRS), and the Social Security Administration (SSA). We have provided information about the matching program in the **SUPPLEMENTARY INFORMATION** section below. The Privacy Act provides an opportunity for interested persons to comment on the matching program. We may defer implementation of this matching program if we receive comments that persuade us to defer