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 Friday.

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


Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13141 Filed 6–1–10; 8:45 am]
BILLING CODE 4160–01–S

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, 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]
BILLING CODE 4160–01–S

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