4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0805]

Dermatologic and Ophthalmic 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: Dermatologic and Ophthalmic 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 February 27, 2012, from 9 a.m. to 5 p.m.

Addresses: FDA is opening a docket for public comment on this meeting. The docket number is FDA-2011-N-0805. The docket will open for public comment on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The docket will close on March 5, 2012. Interested persons may submit electronic or written comments regarding this meeting. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. Submit a single copy of electronic comments or a paper copy of any mailed comments, except that individuals may submit one paper copy. Comments are to be

identified with the docket number found in brackets in the heading of this meeting notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments received on or before February 10, 2012, will be provided to the committee before the meeting.

Location: Hilton Washington DC/Silver Spring (scheduled to be renamed in January 2012 to DoubleTree by Hilton Hotel Washington DC/Silver Spring), 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: DODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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: The committee will be asked to comment on the following topics related to the use of ophthalmic drug products (products intended for use in the eye): 1) Appropriate types of clinical evidence for developing anti-inflammatory drugs for the treatment of postoperative inflammation and reduction of ocular (eye) pain in patients who have undergone ocular surgery. This will include a discussion of the definition and scope of this indication as well as the types of clinical trials needed to support approval; and 2) appropriateness of marketing a single bottle of

ophthalmic product for use in both eyes for postsurgical indications as it relates to the potential risk for infection. FDA's Center for Drug Evaluation and Research would like the advisory committee to provide advice on the potential risk and approaches to mitigating that risk, including limits to fill size where appropriate.

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. All electronic and written submissions submitted to the Docket (see the Addresses section of this document) on or before February 10, 2012, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Those individuals interested in making 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 February 2, 2012. 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 February 3, 2012.

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 Yvette Waples 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: November 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-29682 Filed 11/16/2011 at 8:45 am; Publication Date: 11/17/2011]