



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Dermatologic and Ophthalmic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee. This meeting was announced in the Federal Register of November 17, 2011 (76 FR 71349). The amendment is being made to reflect a change in the Date and Time, Agenda, and Procedure portions of the document. We are cancelling (Topic 1), the portion of the meeting relating to the 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. The portion of the meeting (Topic 2), relating to the appropriateness of marketing a single bottle of anti-inflammatory ophthalmic products for use in both eyes for post-surgical indications as it relates to the potential risk for infection will still be held on the same date (February 27, 2012), the time for the meeting has been changed to 9 a.m. to 3 p.m.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, e-mail: 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.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 17, 2011, FDA announced that a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee would be held on February 27, 2012. On page 71349, in the first column, the Date and Time portion of the document is changed to read as follows:

Date and Time: The meeting will be held on February 27, 2012, from 9 a.m. to 3 p.m.

On page 71349, in the second column, the Agenda portion of the document is changed to read as follows:

Agenda: The committee will be asked to comment on the appropriateness of marketing a single bottle of anti-inflammatory ophthalmic products for use in both eyes for post-surgical indications as it relates to the potential risk for infection. The 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.

On page 71349, in the third column, the third sentence in the Procedure portion of the document is changed to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 8, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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