

a disability, please contact Paul Tran 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: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-5901 Filed 3-14-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0381]

Generic Drug User Fee; Notice of Public Meeting; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 30, 2011, the comment period for the notice of public meeting, published in the **Federal Register** of August 9, 2010 (75 FR 47820), entitled "Generic Drug User Fee; Public Meeting; Request for Comments." In that notice, FDA announced a public meeting that took place on September 17, 2010, to gather stakeholder input on the development of a generic drug user fee program. FDA is reopening the comment period for the expected duration of the active negotiation phase to ensure that all interested stakeholders have the opportunity to share their views on the matter.

DATES: Submit either electronic or written comments by June 30, 2011.

ADDRESSES: 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.

FOR FURTHER INFORMATION CONTACT: Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993, 301-

796-4830, FAX: 301-847-3541, e-mail: peter.beckerman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 9, 2010 (75 FR 47820), FDA published a notice of a public meeting on the development of a generic drug user fee (GDUF) program. In that notice, FDA posed several questions related to a user fee for human generic drugs and sought public input on such a program. The Agency received submissions and presentations from the public meeting, which are now posted on FDA's Web site. On November 4, 2010 (75 FR 67984), FDA subsequently reopened the comment period for 30 days to allow consideration of submissions received after the original docket closing date. Because after that reopening FDA received multiple requests to reopen the docket, including requests from generic industry segments that did not previously comment, FDA reopened the docket again to permit public input on all the submissions.

Interested persons were originally given until October 17, 2010, to comment on the development of a generic drug user fee program. In the last docket reopening on January 24, 2011 (76 FR 4119), FDA reopened the docket to permit comments until February 23, 2011.

To ensure that all interested persons, whether a member of a trade organization at the negotiating table or not, have sufficient opportunity to share their views on the GDUF program throughout the negotiation phase, FDA is reopening the comment period until June 30, 2011. FDA expects that the public component of the GDUF negotiations will be complete by the end of June 2011. Therefore, the Agency is reopening the comment period for this anticipated duration.

II. Additional Information on GDUF

There is information on FDA's Web site that may be useful for interested stakeholders to better understand FDA's effort to establish a generic drug user fee and its current status. Information on the September 17, 2010, public meeting on GDUF, the **Federal Register** notice announcing the meeting, the transcript of the meeting, and slide presentations from the meeting are available at <http://www.fda.gov/Drugs/NewsEvents/ucm224121.htm>. Additional information on that Web page includes subsequent FDA updates, slide presentations, and speeches related to generic drug user fees, and this is also where FDA will post meeting minutes

from the negotiation sessions with industry.

III. How To Submit Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0122]

Center for Devices and Radiological Health 510(k) Implementation: Online Repository of Medical Device Labeling, Including Photographs; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "510(k) Implementation: Discussion of an Online Repository of Medical Device Labeling and of Making Device Photographs Available in a Public Database Without Disclosing Proprietary Information." The purpose of the meeting is to obtain public comment on the following topics: FDA's plans to establish an online public repository of medical device labeling and strategies for displaying device photographs in a public database without disclosing proprietary information.

DATES: *Date and Time:* The public meeting will be held on April 7, 2011, from 8:30 a.m. to 5 p.m.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20903.

Contact Person: Joyce Siwarski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5402, Silver Spring, MD 20903,