

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 April 13, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 April 5, 2011. 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 April 6, 2011.

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 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. 2011-5900 Filed 3-14-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Antiviral 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: Antiviral 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 April 28, 2011, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Paul Tran, 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: 301-847-8540, e-mail: paul.tran@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: On April 28, 2011, the committee will discuss a new drug

application (NDA) 201-917, telaprevir (a hepatitis C virus protease inhibitor), manufactured by Vertex Pharmaceuticals, Inc., with a proposed indication for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin (two medicines approved to treat chronic hepatitis C infection) in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy. Compensated liver disease is a stage in which the liver is damaged but maintains ability to function.

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 April 14, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 April 6, 2011. 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 April 7, 2011.

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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,