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]

BILLING CODE 4160–01–P

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.

[FR Doc. 2011–5917 Filed 3–14–11; 8:45 am]

BILLING CODE 4160–01–P

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,

301–796–5422, FAX: 301–847–8510, e-mail: *Joyce.Siwarski@fda.hhs.gov.*

Registration and Requests for Oral Presentations: Online registration is available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm243829.htm.* Required registration information includes name, title, firm name, address, e-mail, telephone, and fax number, if available. Space is limited, so online registration will close at 5 p.m. on March 31, 2011. You will be notified if you are on a waiting list. If registration is not filled, onsite registration may become available.

If you wish to make an oral presentation during any of the open comment sessions at the meeting, you must indicate this at the time of registration. FDA has included general topics for comment in this document. You should also indicate which topic you wish to address in your presentation. In order to keep each open session focused on the topic at hand, each oral presentation should address only one topic. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is to begin.

Registration is free and will be on a first-come-first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration the day of the public meeting will be provided on a space-available basis beginning at 7:30 a.m. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible.

Requests to make oral presentations, as well as presentation materials, must be sent to the contact person by March 21, 2011. If you need special accommodations due to a disability, please contact Susan Monahan, 301–796–5661 or *Susan.Monahan@fda.hhs.gov,* no later than March 31, 2011.

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Devices and Radiological Health (CDRH) is exploring the development of a searchable medical device labeling repository that would be accessible by the public and provide useful product information to patients and health care practitioners. This might be similar to the labeling repository specific to drugs that is already available through DailyMed on the National Library of Medicine's Web site (*http://www.dailymed.nlm.nih.gov/dailymed/about.cfm*). The repository could eventually cover all classes of devices and could facilitate patient access to information on what types of devices are available for their medical condition and how the devices could be used. It could also assist health care professionals to access labeling that may not always accompany a medical device.

FDA anticipates benefits for device manufacturers, including improved information about potential predicate devices. The labeling available in the repository might cover specific highlighted areas, such as indications for use, operational instructions, warning and precautions, and basic maintenance and cleaning. There might also be a photo of the device and any acceptable accessories. We anticipate that the repository would not include service and technical manuals or supply any proprietary information.

CDRH is holding a public meeting to discuss any comments, concerns, or questions the public may have about putting all device labeling onto one Web site and to solicit input from the public on what they would want and need in labeling and how they would want to access it. CDRH is also interested in learning more about how patients, consumers, and caregivers acquire and use medical device labeling and is seeking input about the circumstances under which patients, consumers, and caregivers receive or should receive risk-benefit information and instructions for use for prescription and over-the-counter devices. In addition, CDRH seeks input on which types of medical devices need patient labeling and what elements that labeling should include. CDRH is also interested in learning what resources, such as guidance or training, the public would like it to provide in order to improve the quality of professional and patient labeling.

The second topic to be discussed during this meeting is that of public access to photographs of cleared medical devices. The CDRH Preliminary Internal Evaluations 510(k) Working Group Report of August 2010 recommended that nonproprietary photos be made available in a public database. In considering how to address this recommendation, CDRH recognizes the sensitivity and potential confidentiality issues with photos that would be made publicly available. Accordingly, CDRH is interested in seeking feedback regarding the implementation of this recommendation, including what guidance is needed to better ensure that this recommendation may be implemented consistently and in a manner that is useful to the public without adverse impact on industry.

II. Comments

FDA is holding this public meeting to obtain information on a number of issues regarding FDA's plans to establish an online public repository of medical device labeling and strategies for displaying device photographs available in a public database without disclosing proprietary information. FDA believes development of a searchable online labeling repository holds many potential benefits for industry, consumers, and health care providers. However, FDA is aware of the concerns some members of industry have expressed about the costs of submitting labeling to FDA. FDA is particularly interested in comments on the costs and benefits of establishing an online labeling repository and is soliciting comments on the following issues:

1. FDA has statutory authority to require the annual submission of updated device labeling as part of the annual registration and listing process under section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)). FDA could rely on this authority to develop a device labeling repository. An alternative approach would be to link to labeling contained on manufacturers' Web sites; however, information about devices no longer being marketed may not be maintained on those sites. What are the advantages and disadvantages of these alternative approaches? Do other alternatives exist to developing a searchable online device labeling repository?

2. "Labeling" is a broad term that can cover practitioner labeling, patient labeling, instructional manuals, and other materials. What types of labeling should be included in an online repository?

3. There is currently no regulation mandating the content and format of labeling for most devices. How can FDA define the type of labeling that must be included in the repository to ensure consistency across products and to ensure the most important information is included in the repository?

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments up to 4 weeks before and after the public workshop (March 10, 2011, through May 10, 2011) regarding

this document. 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. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. In addition, when responding to specific discussion topics as outlined in this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5950 Filed 3–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0110]

Extension of Memorandum of Understanding Between the Food and Drug Administration and Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria of the United Mexican States Concerning Entry of Mexican Cantaloupes Into the United States of America

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an extension of memorandum of understanding (MOU) between FDA and Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria of the United Mexican States. The purpose of the MOU is to establish, and build confidence in, a system that increases the likelihood that cantaloupes from Mexico offered for import into the United States comply with U.S. law. This MOU also establishes a risk-based classification system for firms in Mexico producing cantaloupes for import into the United States to protect the public health.

DATES: The agreement became effective on October 26, 2005, amended on April 19, 2007, and extended on October 28, 2010, for 1 year.

FOR FURTHER INFORMATION CONTACT: Naomi Kawin, Office of Global Engagement, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 3416, Silver Spring, MD 20993–0002, 301–796–8372, FAX: 301–595–7941.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the Agency is publishing notice of this MOU.

Dated: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P