and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these Acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA approved for marketing the animal drug product CONVENIA (cefovecin sodium). CONVENIA is indicated for the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Pasteurella multocida* in cats; and the treatment of skin infections (secondary superficial pyoderma, abscesses and wounds) caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G) in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CONVENIA (U.S. Patent No. 6,020,329) from Pfizer, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 2, 2009, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of CONVENIA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CONVENIA is 2,841 days. Of this time, 2,801 days occurred during the testing phase of the regulatory review period, while 40 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the FD&C Act became effective:* July 17, 2000. The applicant claims November 16, 1999, as the date the investigational new animal drug application (INAD) became effective. However, the date that a major health or environmental effects test is begun or the date on which the Agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, is the effective date for the INAD. According to FDA records, July 17, 2000, is the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act:* March 17, 2008. The applicant claims March 15, 2008, as the date the new animal drug Application (NADA) for CONVENIA (NADA 141–285) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141–285 was March 17, 2008, which is considered to be the initially submitted date for NADA 141–285.

3. *The date the application was approved:* April 25, 2008. FDA has verified the applicant's claim that NADA 141–285 was approved on April 25, 2008. This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,462 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 28, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 26, 2011.

To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See *H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.*) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011–10379 Filed 4–28–11; 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; Public Meeting; Request for Comments

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 to provide a public update and to gather additional stakeholder input on the development of a generic drug user fee program. A user fee program could provide necessary supplemental funding, in addition to current Congressional appropriations, to facilitate the timely review of human generic drug applications by FDA, and FDA is currently in negotiations with the regulated industry aimed at providing a consensus proposal for congressional consideration. In the interest of transparency, and to assure that all interested stakeholders' views are heard and considered, whether they are present at the negotiations or not, FDA is holding a public meeting to

provide an update on the current process and to gather additional input on such a program.

Date and Time: The public meeting will be held on May 10, 2011, from 2 p.m. to 3:30 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 1, Conference Rooms 4101, 4103, and 4105, Silver Spring, MD 20993–0002.

Contact Person: Mari Long, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4237, Silver Spring, MD 20993–0002, 301–796–7574, Fax 301–847–3541, *mari.long@fda.hhs.gov;* or

Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993–0002, 301–796–4830, Fax 301–847–3541, *peter.beckerman@fda.hhs.gov.*

Registration and Requests for Oral Presentations: If you wish to attend and/or present at the meeting, please e-mail your registration information to *GDUFA_Meeting2@fda.hhs.gov* by May 3, 2011. Your e-mail should contain complete contact information for each attendee, including name, title, affiliation, address, e-mail address, and telephone number. 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 as well as the total number of participants, based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak, and if the entire meeting time is not needed for presentations, FDA reserves the right to terminate the meeting early.

If you need special accommodations because of disability, please contact Mari Long or Peter Beckerman (*see Contact Person*) at least 7 days before the meeting.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document by June 10, 2011. To ensure consideration, all comments must be received by June 10, 2011. Submission of comments prior to the meeting is strongly encouraged. Submit any comments that you plan to present at the public meeting to the docket by the date of the public meeting, but note that either electronic or written comments generally may be submitted until June 10, 2011.

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. 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a public meeting related to generic drug user fees. The Agency continues to solicit comment on whether to seek a user fee program that would provide additional resources for the review of human generic drug applications, as well as what such a program should look like. New legislation would be required for FDA to establish and collect user fees for generic drugs, and FDA is currently engaged in negotiations with industry over aspects of a joint proposal for a generic drug user fee program, including fees and performance goals. Because FDA can only negotiate with trade organizations, not individual companies, but remains interested in hearing from non-affiliated companies in addition to patient and consumer stakeholders, the Agency will hold a public meeting. The public meeting will provide a status update and seek input from stakeholders on generic drug user fees. In addition, FDA continues to encourage all interested stakeholders to submit either electronic or written comments to the docket (*see Comments*).

II. What information should you know about the public meeting, when and where will the public meeting occur, and what format will FDA use?

Through this notice, we are announcing a public meeting to update stakeholders and hear stakeholder views on what features FDA should propose for a generic drug user fee program. We will conduct the meeting on May 10, 2011, from 2 p.m. to 3:30 p.m. at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 1, Conference Rooms 4101, 4103, and 4105, Silver Spring, MD 20993–0002. In general, the meeting format will include a presentation by FDA and presentations by stakeholders and members of the public who have registered in advance to present at the meeting. The amount of time available for presentations will be determined by the number of people who register to make a presentation. We will also provide an opportunity for organizations and individuals to submit either electronic or written comments to the docket after the meeting (*see Comments*). FDA policy issues are beyond the scope of this initiative. Accordingly, the presentations should focus on process and funding issues, and not focus on policy.

Dated: April 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10382 Filed 4–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Brain Disorders Pathology and Treatment.

Date: May 26, 2011.

Time: 11 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dan D. Gerendasy, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7843, Bethesda, MD 20892. 301–408–9164. *gerendad@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cancer Biology and Therapeutics.

Date: June 1–2, 2011.

Time: 11 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)