DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1347]

Determination of Regulatory Review Period for Purposes of Patent Extension; AVELOX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AVELOX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human 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 Commissioner 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 a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product AVELOX (moxifloxacin hydrochloride). AVELOX is indicated for uncomplicated skin and skin structure infections. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AVELOX (U.S. Patent No. 4,490,517) from Bayer Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of AVELOX represented the first permitted commercial marketing or use of the product. Shortly 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 AVELOX is 1,435 days. Of this time, 1,069 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: January 7, 1996. The applicant claims January 27, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 7, 1996, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: December 10, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for AVELOX (NDA 21–085) was initially submitted on December 10, 1998.

3. *The date the application was approved*: December 10, 1999. FDA has verified the applicant's claim that NDA 21–085 was approved on December 10, 1999.

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 889 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by April 29, 2002. 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 August 27, 2002. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the 2 docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 24, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–4748 Filed 2–27–02; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Allergenic Products 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 March 15, 2002, from 8 a.m. to 4:15 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Pearline Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 15, 2002, the committee will hear updates on: (1) Personnel and lot release activities of the Laboratory of Immunobiochemistry (LIB), (2) LIB research programs, (3) particulates in allergen extracts, (4) reduction of possible risk of exposure to transmissible spongiform encephalopathy (TSE) agents in allergen extracts, and (5) the statistical power of clinical studies used to assess bioequivalence of allergen extracts. The committee will discuss: (1) Considerations for the regulation of recombinant allergens for the diagnosis and treatment of allergic disease, and (2) glycerol in allergen extracts.

Procedure: On March 15, 2002, from 8 a.m. to 3:15 p.m., the meeting is open to the public. 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 by March 7, 2002. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12 noon, and between 2:45 p.m. and 3:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 7, 2002, 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.

Closed Committee Deliberations: On March 15, 2002, from approximately 3:15 p.m. to 4:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion will be closed to permit discussion of the report of the site visit review of the Laboratory of Immunobiochemistry, in the Division of Bacterial, Parasitic & Allergenic Products, in the Office of Vaccines Research and Review, Center for Biologics Evaluation and Research.

Persons attending FDA 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 William Freas or Pearline Muckelvene at least 7 days in advance of meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 22, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–4686 Filed 2–27–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products 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: Blood Products 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 March 14, 2002, from 8 a.m. to 5:30 p.m. and on March 15, 2002, from 8 a.m. to 4 p.m.

Location: Gaithersburg Holiday Inn, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 14, 2002, the following committee updates are tentatively scheduled: (1) Nucleic acid testing for whole blood, including standards for human immune deficiency virus and hepatitis C virus RNA; (2) nucleic acid testing for parvovirus B19; (3) nucleic acid testing for hepatitis A virus; and (4) announcement of planned FDA workshops. The committee will hear an informational presentation on emergency preparedness for the blood supply. In the afternoon, the committee will hear presentations, discuss and make recommendations on percutaneous exposure of blood and plasma donors: Tattoos and body piercing. On March 15, 2002, the committee will hear informational presentations and have discussion on the review of data supporting extension of the dating period for platelets, and in the afternoon, bacterial and fungal safety of tissue.

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 by March 1, 2002. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m., and 3:45 p.m. and 4:45 p.m. on March 14, 2002, and between approximately 9:30 a.m. and 10 a.m., and 2:30 p.m. and 3 p.m. on March 15, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 1, 2002, 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.

Persons attending FDA's advisory committees 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 Linda A. Smallwood, or Jane Brown at 301–827–1296 at least 7 days in advance of meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 22, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–4680 Filed 2–27–02; 8:45 am]

BILLING CODE 4160–01–S