Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 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 Lotemax™ and Alrex™ (loteprednol etabonate). Lotemax™ is indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, conrnea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selective infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable dimunition in edema and inflammation. Alrex™ is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lotemax™ and Alrex™ (U.S. Patent No. 4,996,335) from Nicholas S. Bodor, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Lotemax™ and Alrex™ 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 Lotemax™ and Alrex™ is 3,092 days. Of this time, 2,017 days occurred during the testing phase of the regulatory review period, while 1,075 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:* September 22, 1989. The applicant claims January 2, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 22, 1989, 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:* March 31, 1995. The applicant claims March 29, 1995, as the date the new drug application (NDA) for Lotemax™ and Alrex™ (NDA 20–583) was initially submitted. However, FDA records indicate that NDA 20–583 was submitted on March 31, 1995.

3. *The date the application was approved:* March 9, 1998. FDA has verified the applicant's claim that NDA 20–583 was approved on March 9, 1998.

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 1,284 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 15, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 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: May 4, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–12392 Filed 5–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Subcommittee of the Biological Response Modifiers 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: Subcommittee of the Biological Response Modifiers 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 June 3, 1999, 8:30 a.m. to 6 p.m., and June 4, 1999, 8 a.m. to 3 p.m.

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

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, 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 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 3 and 4, 1999, the Xenotransplantation Subcommittee will discuss the following public health issues concerning porcine xenotransplantation: (1) Update of scientific data concerning porcine endogenous retrovirus, (2) update of patient monitoring and screening data concerning patients who have received a porcine xenograft, (3) update on FDA xenotransplantation policy development, and (4) proposals for solid organ xenotransplantation.

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 May 27, 1999. Oral presentations from the public will be scheduled between approximately 8:45 a.m. to 9:15 a.m. and 5:30 p.m. to 6 p.m. on June 3, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 20, 1999, 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.

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

Dated: May 12, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–12519 Filed 5–13–99; 4:24 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA 225–99–4000]

Memorandum of Understanding Between the Food and Drug Administration and the U.S. Army Medical Research and Material Command

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the U.S. Army Medical Research and Material Command. The purpose of the MOU is to define responsibilities during the research, development, and pre-marketing acquisition of medical material for military applications.

DATES: The agreement became effective November 16, 1998.

FOR FURTHER INFORMATION CONTACT: Steven M. Solomon, Office of Regulatory Affairs (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0386.

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

Dated: May 11, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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