

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 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 ENABLEX (darifenacin hydrobromide). ENABLEX is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ENABLEX (U.S. Patent No. 5,096,890) from Novartis International Pharmaceutical Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ENABLEX 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 ENABLEX is 3,824 days. Of this time, 3,073 days occurred during the testing phase of the regulatory review period, while 751 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:* July 6, 1994. The applicant claims June 13, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 6, 1994, 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 3, 2002. The applicant claims December 30, 2002, as the date the new drug application (NDA) for ENABLEX (NDA 21-513) was initially submitted. However, FDA records indicate that NDA 21-513 was submitted on December 3, 2002.

3. *The date the application was approved:* December 22, 2004. FDA has verified the applicant's claim that NDA

21-513 was approved on December 22, 2004.

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 2,298 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*) written or electronic comments and ask for a redetermination by March 31, 2006. 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 July 31, 2006. 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: January 5, 2006.

**Jane A. Axelrad,**

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

[FR Doc. E6-1072 Filed 1-27-06; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. 2004E-0021]**

#### **Determination of Regulatory Review Period for Purposes of Patent Extension; XOLAIR**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for XOLAIR 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (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 V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6681.

**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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 a human biological 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 biological product XOLAIR (omalizumab). XOLAIR is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive

skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled by inhaled corticosteroids. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XOLAIR (U.S. Patent No. 6,267,958) from Genentech, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 8, 2005, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of XOLAIR 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 XOLAIR is 3,440 days. Of this time, 2,329 days occurred during the testing phase of the regulatory review period, while 1,111 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* January 20, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 20, 1994.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act:* June 5, 2000. The applicant claims June 2, 2000, as the date the product license application (BLA) for XOLAIR (BLA 103976/0) was initially submitted. However, FDA records indicate that BLA 103976/0 was submitted on June 5, 2000.

3. *The date the application was approved:* June 20, 2003. FDA has verified the applicant's claim that BLA 103976/0 was approved on June 20, 2003.

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 463 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**) written or

electronic comments and ask for a redetermination by March 31, 2006. 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 July 31, 2006. 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: January 6, 2006.

**Jane A. Axelrad,**

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

[FR Doc. E6–1078 Filed 1–27–06; 8:45 am]

**BILLING CODE 4160–01–5**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Anti-Infective 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:* Anti-Infective 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 March 6, 2006, from 8:30 a.m. to 5 p.m.

*Location:* Food and Drug Administration, Center for Drug Evaluation and Research, Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Cathy A. Groupe, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm.

1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: [GroupeC@cder.fda.gov](mailto:GroupeC@cder.fda.gov), or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512530. Please call the information line for up-to-date information on this meeting.

*Agenda:* The committee will discuss new drug application (NDA) 21–572/S–008, CUBICIN (daptomycin for injection 500 mg/vial), Sponsor Cubist Pharmaceuticals, for the proposed indication of the treatment of *Staphylococcus aureus* bacteremia, including those with known or suspected endocarditis caused by methicillin-susceptible and methicillin-resistant strains.

The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under heading "Anti-Infective Drugs Advisory Committee (AIDAC)." (Click on the year 2006 and scroll down to AIDAC meetings.)

*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 February 27, 2006. Oral presentations from the public will be scheduled between 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 27, 2006, 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 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 Cathy A. Groupe at least 7 days in advance of the meeting.

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