

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 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 XIGRIS (droctrecogin alpha). XIGRIS is indicated for the reduction of mortality in adult patients with severe sepsis (sepsis associated with severe organ dysfunction) who have a high risk of death. Subsequent to this approval, the Patent and Trademark Office received three patent term restoration applications for XIGRIS (U.S. Patent Nos. 4,775,624; 5,681,932; and 5,270,040) from Eli Lilly & Co., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated December 30, 2002, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of XIGRIS 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 XIGRIS is 2,493 days. Of this time, 2,193 days occurred during the testing phase of the regulatory review period, while 300 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 26, 1995. The applicant claims January 25, 1995, as the date the investigational new drug

application (IND) became effective. However, FDA records indicate that the IND effective date was January 26, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* January 26, 2001. FDA has verified the applicant's claim that the biological license application (BLA) for XIGRIS (BLA 125029/0) was initially submitted on January 26, 2001.

3. *The date the application was approved:* November 21, 2001. FDA has verified the applicant's claim that BLA 125029/0 was approved on November 21, 2001.

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 1,397 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written comments and ask for a redetermination by January 26, 2004. 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 May 24, 2004. 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: October 30, 2003.

**Jane A. Axelrad,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2001P–0075]

### Joint Meeting of the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs; 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 Committees:*  
Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs.

*General Function of the Committees:*  
To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on December 16, 2003, from 8 a.m. to 5 p.m.

*Addresses:* Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "01P–0075—Switch Status of Emergency Contraceptives from Rx to OTC" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Location:* Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Karen M. Templeton-Somers, 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, or e-mail: [SomersK@cder.fda.gov](mailto:SomersK@cder.fda.gov), or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) codes 12541 and 12537. Please call the Information Line for up to date information on this meeting.

*Agenda:* The committees will consider the safety and efficacy of new drug application 21–045, proposing over-the-counter use of Plan B (levonorgestrel), Women's Capitol Corp., for reducing the chance of pregnancy after unprotected sex (if contraceptive failed or if birth control was not used). The sponsor proposes a 0.75 milligram (mg) tablet taken as soon as possible, but no later than 72 hours after unprotected