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.

[FR Doc. 03–29333 Filed 11–24–03; 8:45 am]

BILLING CODE 4160–01–S

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*, 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

sex with a second 0.75 mg tablet taken 12 hours after the first tablet.

The background material will become available no later than the day before the meeting and will be posted under the Nonprescription Drugs Advisory Committee (NDAC) docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2003 and scroll down to NDAC meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions must be made to the contact person by December 5, 2003. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 5, 2003, 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 Karen Templeton-Somers 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).

Dated: November 17, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–29334 Filed 11–24–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Listing of Grants for Research Projects

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Section 52.1(b) of the regulations governing grants for research projects, codified at 42 CFR part 52, provides that the Secretary of Health and Human Services will periodically publish a list of all of the research project grant programs to which the research project grant regulations apply. This Notice provides the most recent list of the programs covered by the regulations and supersedes and replaces the prior Notice published October 24, 1996 (61 FR 55102–55106).

EFFECTIVE DATE: November 25, 2003.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20892, telephone (301) 496–4607 (not a toll-free number), fax (301) 402–0169, e-mail *jm40z@nih.gov.*

SUPPLEMENTARY INFORMATION: The National Institutes of Health (NIH) published a final rule in the **Federal Register** on October 24, 1996 (61 FR 55102–55106), amending the regulations at 42 CFR part 52, Grants for Research Projects, which govern Public Health Service (PHS) research project grants. The regulations were amended to apply to all research project grant programs administered by NIH and the Department of Health and Human Services (Department), except for grants for health services research, demonstration, and evaluation projects administered by the Agency for Health Care Policy and Research (AHCPR), to make it unnecessary to include a long list of programs in the regulations or to go through the lengthy process of amending the regulations each time a new program is established. At that time we provided in the preamble a listing of the applicable programs and indicated that we would periodically publish a list of the research project grant programs to which the regulations apply, and the applicability of the regulations to new programs would be announced as Department components initiated new programs.

We are publishing the list of programs to which the regulations apply to reflect the addition of new authorities in sections 317J, 317K, 317L, 330E, 399M, 399N, 409E, 434A, 445I, 447B, and 1261 of the Public Health Service Act (PHS Act), as amended. Section 317J of the PHS Act (42 U.S.C. 247b–11), as amended by section 601 of the Children's Health Act of 2000, Public Law 106–310, concerns research with respect to education and training for health professionals and the general public relating to the effects of folic acid in preventing birth defects. Section 317K of the PHS Act (42 U.S.C. 247b–12), as amended by section 901 of Public Law 106–310, concerns research relating to risk factors, prevention strategies, and the roles of the family, health care providers, and the community in safe motherhood. Section 317L of the PHS Act (42 U.S.C.247b–13), as amended by section 911 of Public Law 106–310, concerns epidemiological research on the prevention of prenatal and postnatal smoking, alcohol, and illegal drug use. Section 330E of the PHS Act (42 U.S.C. 254c–5), as amended by section 801 of Public Law 106–310, concerns research relating to intervention strategies to improve the lives of persons with epilepsy, particularly children. Section 399M of the PHS Act (42 U.S.C. 280g–1), as amended by section 702 of Public Law 106–310, concerns research relating to the efficacy of new screening techniques and technology, including clinical studies on the efficacy of new interventions, regarding hearing loss in infants. Section 399N of the PHS Act (42 U.S.C. 280g–2), as amended by section 1101 of Public Law 106–310, concerns research relating to improving the outcomes among children with childhood cancers and resultant secondary conditions. Section 409E of the PHS Act (42 U.S.C. 284i), as amended by section 1901 of Public Law 106–310, concerns research relating to autoimmune diseases. Section 434A of the PHS Act (42 U.S.C. 285c–9), as amended by section 402 of Public Law 106–310, concerns long-term epidemiology studies relating to type 1 or juvenile diabetes. Section 445I of the PHS Act (42 U.S.C. 285e–10a), as added by section 801 of the Public Health Improvement Act, Public Law 106–505, concerns Alzheimer's Disease Clinical Research and Training Awards to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care, and treatment of individuals with Alzheimer's disease. Section 447B of the PHS Act (42 U.S.C. 285f–3), as amended by section 901 the Public Health Improvement Act, Public Law 106–505, concerns Sexually Transmitted Disease Clinical Research and Training Awards to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care, and treatment of individuals with sexually transmitted diseases. Finally, section 1261 of the PHS Act (42 U.S.C. 300d–61), as amended by section 1303 of Public Law 106–310, concerns basic and applied research regarding traumatic brain injury, including the development, modification, and evaluation of therapies and programs of rehabilitation toward reaching or restoring normal capabilities.