Federal Communications Commission.

Gary Michaels,

Chief, Legal Branch, Auctions and Industry Analysis Division.

[FR Doc. 03–29449 Filed 11–24–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 03–14]

Revocation of Licenses and Order To Discontinue Operations in U.S.—Foreign Trades for Failure To Comply With the Requirements of the Ocean Shipping Reform Act of 1998; Notice of Show Cause Proceeding

November 20, 2003.

Notice is given that, on November 17, 2003, the Federal Maritime Commission (''Commission'') served an Order to Show Cause (''Order'') on fourteen (14) non-vessel-operating common carrier (''NVOCC'')/ocean transportation intermediaries (''OTIs'').

Commission regulations require that each NVOCC in the United States must be licensed and, among other requirements, file a Form FMC–1 indicating the location of its electronically published tariff. The 14 NVOCCs listed in the Commission's Order each maintain an OTI license issued by the Commission, but have otherwise failed to establish or maintain an electronically published tariff and to maintain a current Form FMC–1 on file with the Commission. The Commission now proposes to revoke the licenses of these NVOCCs for said failures, and to direct them to cease and desist from operating in the U.S.-foreign trades.

The Order directs the 14 NVOCCs to show cause why the Commission should not revoke their respective licenses for failure to comply with sections 8 and 19 of the Shipping Act of 1984, 46 U.S.C. app. § 1707 and § 1718, as amended, and 46 CFR part 515.

The Order's full text may be viewed on the Commission's Home page at *http://www.fmc.gov,* or at the Office of the Secretary, Room 1046, 800 N. Capitol Street, NW., Washington, DC. Any person having an interest and desiring to intervene in this proceeding shall file a petition for leave to intervene in accordance with Rule 72 of the Commission's Rules of Practice and Procedure, 46 CFR 502.72, and the procedural schedule set forth in the Commission's November 17, 2003 Order.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–29415 Filed 11–24–03; 8:45 am]

BILLING CODE 6730–01–P

GENERAL SERVICES ADMINISTRATION

Office of Governmentwide Policy; Revision of a Standard Form by the Department of the Treasury

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Notice.

SUMMARY: The Department of the Treasury revised SF 3881, ACH Vendor/Miscellaneous Payment Enrollment to:

Remove the CTP checkbox and the OMB expiration; and

Authorize form for local reproduction. This was due to low demand in the Federal Supply Service.

You can obtain the updated form in two ways:

On the internet. Address: *http://w3.gsa.gov/web/c/newform.nsf/MainMenu?OpenForm* or;

From GSA, Forms-MCF, Attn.: Barbara Williams, (202) 501–0581.

FOR FURTHER INFORMATION CONTACT: Ms. Lois Holland (202) 622–1563. This contact is for information about completing the form only.

DATES: Effective November 25, 2003.

Dated: November 18, 2003.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer, General Services Administration.

[FR Doc. 03–29362 Filed 11–24–03; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice; correction.

SUMMARY: The Office of the Secretary, HHS, published a notice in the **Federal Register** of November 10, 2003, concerning a finding of scientific misconduct regarding Dr. Gelband. The document contained a typographical error.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 301–443–5330.

Correction

In the **Federal Register** of November 10, 2003, in FR Doc. 03–28197, on page 63799 in the first column at letter ''B'' replace the first sentence to read: ''Hypertension 2000 paper #2: Figure 1A merited retraction.''

Dated: November 18, 2003.

Lawrence J. Rhoades,

Acting Director, Office of Research Integrity.

[FR Doc. 03–29335 Filed 11–24–03; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2002E–0099, 2002E–0184, and 2003E–0255]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XIGRIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of three applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of three patents which claim 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, 240–453–6699.

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 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