DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following committee meeting.

NAME: Mine Safety and Health Research Advisory Committee (MSHRAC).

TIME AND DATE: 9 a.m.–4 p.m., June 10, 1999.

PLACE: Spokane Research Laboratory, 315 East Montgomery Avenue, Spokane, Washington 99207.

STATUS: Open to the public, limited only by space available. The meeting room accommodates approximately 50 people.

PURPOSE: The Committee is charged with advising the Secretary; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; and the Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), section 102(b)(2).

MATTERS TO BE DISCUSSED: Agenda items include Deputy Director's comments; Associate Director-Mining comments; Mining Request for Applications (RFA) History/Review; Diesel Partnership Discussion; Feedback on Mining RFA; Spokane Research Laboratory Mine Injury and Disease Prevention Branch Overview; Mine Emergency Preparedness and Response Subcommittee; Achieving Organizational Excellence; and future activities of the Committee.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Larry Grayson, Ph.D., Executive Secretary, MSHRAC, NIOSH, CDC, 200 Independence Avenue, SW, Room 715–H, Humphrey Building, Washington, DC 20201, telephone 202/401–2192, fax 202/260–4464.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 13, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–12544 Filed 5–18–99; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

NAME: Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH).

TIME AND DATE: 9 a.m.–4 p.m., June 8, 1999.

PLACE: The Washington Court, 525 New Jersey Avenue, NW, Washington, DC 20001–1527.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

PURPOSE: The BSC, NIOSH is charged with providing advice to the Director, NIOSH on NIOSH research programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings, and disseminating results.

MATTERS TO BE DISCUSSED: Agenda items include a report from the Director of NIOSH; National Occupational Research Agenda (NORA) update; Feedback on Medical Surveillance Report; Evaluation of NIOSH Internet Activities; The Changing Nature of Work; Flock Workers' Lung; Surveillance Activities; and future activities of the Board.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Bryan D. Hardin, Ph.D., Executive Secretary, BSC, NIOSH, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–3773, fax 404/639–2170, e-mail: bdh1@cdc.gov.

The Director, Management Analysis and Services Office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 13, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–12543 Filed 5–18–99; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0615]

Determination of Regulatory Review Period for Purposes of Patent Extension; Neumega®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Neumega® 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological 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 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 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 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 Neumega® (interleukin-11). Neumega® is indicated for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy in patients with nonmyeloid malignancies who are at high risk of severe thrombocytopenia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Neumega® (U.S. Patent No. 5,215,895) from Genetics Institute, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 28, 1998, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Neumega® 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 Neumega® is 1,854 days. Of this time, 1,513 days occurred during the testing phase of the regulatory review period, while 341 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*: October 30, 1992. The applicant claims October 25, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 30, 1992, 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 505 of the act*: December 20, 1996. FDA has verified the applicant's claim that the product license application (PLA) for Neumega® (PLA 96–1433) was initially submitted on December 20, 1996.

3. *The date the application was approved*: November 25, 1997. FDA has verified the applicant's claim that PLA 96–1433 was approved on November 25, 1997.

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 542 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. 99–12527 Filed 5–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0612]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Trovan 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 Commissioner of Patents and 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