announces the following Federal advisory committee meeting.

NAME: National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect (NTFFASFAE).

TIMES AND DATES: 9 a.m.–4:30 p.m., December 6, 2004; 9 a.m.–12 noon, December 7, 2004.

PLACE: Westin Buckhead Atlanta Hotel, 3391 Peachtree Road, NE., 30326, telephone (404) 365–0065, fax (404) 365–8787.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 65 people.

PURPOSE: The Secretary is authorized by the Public Health Service Act, Section 399G, (42 U.S.C. S 280f, as added by Public Law 105–392) to establish a National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect to: (1) Foster coordination among all governmental agencies, academic bodies and community groups that conduct or support Fetal Alcohol Syndrome (FAS) and Fetal Alcohol Effect (FAE) research, programs and surveillance; and(2) to otherwise meet the general needs of populations actually or potentially impacted by FAS and FAE.

MATTERS TO BE DISCUSSED: Agenda items include: An overview of effective strategies to reduce the risk of problem drinking and alcohol-exposed pregnancies; what is needed to implement effective programs in the service delivery system; alcohol advertising and adolescent girls; and a discussion of issues presented. Additional agenda items include: Prevention and Post-Exposure working group sessions; updates from Task Force members on current initiatives; an update on activities from the Interagency Coordinating Committee on Fetal Alcohol Syndrome, the CDC and other Federal agencies; future topics, and scheduling the next meeting.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: R. Louise Floyd,DSN, RN, Designated Federal Official, National Center on Birth Defects and Developmental Disabilities, CDC, 1600Clifton Road, NE., (E–86), Atlanta, Georgia 30333, telephone (404) 498–3923, fax (404) 498–3550.

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 CDC and ATSDR.

Dated: October 27, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–24391 Filed 11–1–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry

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) and the National Center for Environmental Health/Agency for Toxic Substances Disease Registry (ATSDR) announce the following committee meeting:

Name: Board of Scientific Counselors (BSC), National Center for Environmental Health/Agency for Toxic Substances andDisease Registry (NCEH/ATSDR).

Time and Dates: 8:30 a.m.–5 p.m., November 18, 2004, 8:30 a.m.–12:30 p.m., November 19, 2004.

Place: CDC Headquarters facility, 1600 Clifton Road, Atlanta, GA 30333.

Status: Open to the public for observation, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: The Secretary, and by delegation, the Director of the Centers for Disease Control and Prevention and the Administrator of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, are authorized under section 301 (42 U.S.C. 241) and section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to (1) conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist States and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and well-being; and (3) train State and local personnel in health work. The Board of Scientific Counselors, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agencies' mission to protect and promote people's health. The Board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The Board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Matters To Be Discussed: The agenda items for the meeting on November 18–19, 2004, will include but are not limited to an update on future initiatives; update on NCEH/ATSDR consolidation and accomplishments; reports on the Program Peer Review and the Community and Tribal subcommittees and the Health Department Workgroup; update on NCEH/ATSDR strategic priorities; report on social/behavioral sciences at NCEH/ATSDR; a review of the ATSDR Draft Dioxin Soil Policy Guidelines; and a presentation on the Emergency Preparedness and Response activities at NCEH/ATSDR.

Agenda items are tentative and subject to change.

For Further Information Contact: Individuals interested in attending the meeting, please contact Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, 1600 Clifton Road, Mail Stop E–28, Atlanta, GA 30303; telephone 404/498–0003, fax 404/498–0059; e-mail: *smalcom@cdc.gov.* The deadline for notification of attendance is November 12, 2004.

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 CDC and the National Center for Environmental Health/Agency for ToxicSubstances and Disease Registry.

Dated: October 27, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–24389 Filed 11–1–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002E–0340]

Determination of Regulatory Review Period for Purposes of Patent Extension; GANIRELIX ACETATE INJECTION (Formerly ANTAGON)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GANIRELIX ACETATE INJECTION 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 that claims that human drug 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 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 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 GANIRELIX ACETATE INJECTION (ganirelix acetate). GANIRELIX ACETATE INJECTION is indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GANIRELIX ACETATE INJECTION (U.S. Patent No. 4,801,577) from Syntex, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 30, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GANIRELIX ACETATE INJECTION represented the first permitted commercial marketing or use of the product. 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 GANIRELIX ACETATE INJECTION is 3,558 days. Of this time, 3,376 days occurred during the testing phase of the regulatory review period, while 182 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*: November 2, 1989. The applicant claims October 3, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 2, 1989, 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*: January 29, 1999. The applicant claims January 28, 1999, as the date the new drug application (NDA) for GANIRELIX ACETATE INJECTION (NDA 21–057) was initially submitted. However, FDA records indicate that NDA 21–057 was submitted on January 29, 1999.

3. *The date the application was approved*: July 29, 1999. FDA has verified the applicant's claim that NDA 21–057 was approved on July 29, 1999.

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 5 years 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 January 3, 2005. 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 2, 2005. 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 (see **ADDRESSES**). 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 15, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–24378 Filed 11–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG 2004–19483]

Review and Approval of Classification Societies

AGENCY: Coast Guard, DHS.

ACTION: Notice of policy; request for comments.

SUMMARY: This notice contains procedures the Coast Guard will use to review classification societies seeking Coast Guard approval to perform certain functions for vessels. Under the 2004 Coast Guard and Maritime Transportation Authorization Act, after January 1, 2005, classification societies may not perform those certain functions for vessels unless they are either approved by the Coast Guard or are full members of the International Association of Classification Societies. Class societies seeking Coast Guard approval should submit a package in accordance with the procedures in this notice. The Coast Guard also seeks public comment on the procedures described herein for reviewing and approving classification societies.

DATES: This notice of policy is effective November 2, 2004. Comments and related material must reach the Docket Management Facility on or before January 3, 2005.

ADDRESSES: