Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 15 people. Call the ATSDR/ORR field office for the conference bridge line and access code.

Background: A Memorandum of Understanding (MOU) was signed in October 1990 and renewed in September 2000 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ASuperfund@). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 2000, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC. Community involvement is a critical part of ATSDR's and CDC's energy-related research and activities, and input from members of the ORRHES is part of these efforts.

Purpose: The purpose of this meeting is to address issues that are unique to community involvement with the ORRHES, and agency updates.

Matters To Be Discussed: Agenda item will include a discussion on the draft TSCA Public Health Assessment, comments from the Exposure Investigation Workgroup, and updates from the Agency.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Marilyn (Palmer) Horton, Designated Federal Official and Health Communications Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE M/S E–32 Atlanta, Georgia 30333, telephone 1–888–42–ATSDR (28737), fax 404/498–1744.

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 ATDSR.

Dated: April 15, 2005.

Alvin Hall,

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

[FR Doc. 05–7994 Filed 4–20–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Children, Youth and Families 2005 Head Start Tribally Controlled Land Grant College and University Partnerships; Notice of Correction for the FY 05 Head Start Tribally Controlled Land Grant College and University Partnerships Program Announcement, HHS–2005–ACF–ACYF–YT–0012, CFDA# 93.600

AGENCY: Administration on Children, Youth and Families, Head Start Bureau, ACF, DHHS.

ACTION: Notice of corrections.

SUMMARY: This notice is to inform interested parties of corrections to the Head Start Tribally Controlled Land Grant College and University Partnerships Program Announcement that was published on Wednesday, April 13, 2005. The following corrections should be noted:

(1) Under Priority Areas I, Section VII. Agency Contacts, Program Office Contact, please delete the following name, address, phone number, and e-mail address: Katherine Gray, U.S. Department of Health and Human Services, Administration for Children and Families, ACYF—Head Start Bureau, 330 C Street, SW., Switzer Room 2211, Washington, DC 20447. Phone: 312–353–2260. E-mail: *kgray@acf.hhs.gov.*

Please replace the deleted name, address, phone number, and e-mail address with the following: Rosalind Dailey, U.S. Department of Health and Human Services, Administration for Children and Families, ACYF—Head Start Bureau, 330 C Street, SW., Switzer Room 2211, Washington, DC 20447. Phone: 202–205–8653. E-mail: *rdailey@acf.hhs.gov.*

All information in this notice of correction is accurate and replaces information specified in the April 13 notice. Applications are still due by the deadline date that was published in the April 13 notice (May 13 for Letters of Intent or Preapplications and June 13 for Applications).

FOR FURTHER INFORMATION CONTACT: For further information please contact the Administration on Children, Youth and Families, Head Start Bureau at (202) 205–8653 or *rdailey@acf.hhs.gov.*

Dated: April 14, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 05–7949 Filed 4–20–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee; 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 Committee: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on May 13, 2005, from 8 a.m. to 5:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Neel Patel, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8611, ext. 3, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512624. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on FDA's Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in

the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will also discuss and make recommendations regarding general issues for pulse oximeters. The issues include the equivalence of reflectance sensor technology to transmissive sensor technology; validation recommendations for neonatal intended use; and over-the-counter (OTC) use of pulse oximeters.

Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 3, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by May 3, 2005, 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 Shirley Meeks, Conference Management Staff, at 240–276–0450, ext. 105, 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: April 13, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–7948 Filed 4–20–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0410]

Guidance for Industry and Food and Drug Administration Staff on Application User Fees for Combination Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled ''Application User Fees for Combination Products.'' This document provides guidance to industry and FDA staff on marketing application user fees for combination products. The guidance also describes how the ''barrier to innovation'' waiver provision under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the act) may be applied to innovative combination products in the infrequent situation where FDA requires the submission of two marketing applications.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for copies of this guidance to the Office of Combination Products (HFG–3), 15800 Crabbs Branch Way, Rockville, MD 20855, or FAX: 301–427–1935. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments concerning this guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Application User Fees for Combination Products.'' In the **Federal Register** of September 28, 2004 (69 FR 57942), FDA issued a notice of availability of a draft guidance document covering the same topic.

As defined under 21 CFR 3.2(e), a combination product is a product comprised of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product. Depending upon the type of combination product, approval, clearance, or licensure may be obtained through submission of a single marketing application, or through separate marketing applications for the individual constituent parts of the combination product. For most combination products, a single marketing application is sufficient for the product's approval, clearance, or licensure. In some cases, two marketing applications may be submitted for a combination product when one application would suffice. For example, a sponsor may choose to submit two applications when one would suffice in order to receive some benefit from having two applications. In other cases, FDA may determine that two marketing applications are necessary.

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). PDUFA authorized FDA to collect fees from companies that produce certain human drug and biological products. The Medical Device User Fee and Modernization Act of 2002 amended the act to provide for user fees for the review of device applications. When a company requests approval of a new drug, device, or biological product prior to marketing, it must submit an application along with a fee to support the review process.

This document provides guidance to industry and FDA staff on marketing application user fees for combination products. The guidance document explains that combination products for which a single marketing application is submitted, should be assessed the user fee associated with that particular type of marketing application. The document explains that if a sponsor chooses to submit two marketing applications when one would suffice, a user fee for each application would ordinarily be assessed. The document also explains that in the infrequent situation where FDA requires two marketing applications for a combination product, two application fees would ordinarily be assessed. However, the guidance also describes how the PDUFA ''barrier to innovation'' waiver provision may be applied to innovative combination products for which FDA requires the submission of two marketing applications. Such a waiver would provide a reduction in application user