information within the meaning of the Freedom of Information Act and FDA's implementing regulations (21 CFR 20.61).

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552), as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: May 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10435 Filed 5–20–05; 2:41 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric 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: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of the Department of Health and Human Services (DHHS) under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by DHHS, when that research is also regulated by FDA.

Date and Time: The meeting will be held on Wednesday, June 29, 2005, from 12:30 p.m. to 5 p.m. and on Thursday, June 30, 2005, from 8 a.m. to 5 p.m.

Location: The Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Jan N. Johannessen, Office of Science and Health Coordination of the Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14C–06), Rockville, MD 20857, 301–827–6687, or by e-mail: *jjohannessen@fda.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

Agenda: On Wednesday, June 29, 2005, the committee will hear and discuss the recommendation of the Pediatric Ethics Subcommittee from its meeting on June 28, 2005, regarding a referral by an Institution Review Board of a proposed clinical investigation involving children as subjects that is regulated by FDA and is conducted or supported by DHHS. The committee will also discuss a report by the agency on Adverse Event Reporting, as mandated in section 17 of the Best Pharmaceuticals for Children Act (BPCA), for ethinyl estradiol; norgestimate (ORTHO TRI-CYCLEN), ciprofloxacin (CIPRO), tolterodine (DETROL LA), leflunomide (ARAVE), paricalcitol (ZEMPLAR), zolmitriptan (ZOMIG), dorzolamide (TRUSOPT).

On Thursday, June 30, 2005, the committee will discuss a report by the agency on Adverse Event Reporting, as mandated in section 17 of the BPCA, for methylphendidate (CONCERTA and other methtylphenidates).

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2005 and scroll down to PAC meetings).

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 June 17, 2005. Oral presentations from the public will be scheduled on Wednesday, June 29, 2005, between approximately 3:20 p.m. and 3:50 p.m., and Thursday, June 30, 2005, between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by June 17, 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 notify Jan Johannessen 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: May 19, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–10436 Filed 5–24–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0184]

Pediatric Ethics Subcommittee of the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on certain regulatory issues with regard to FDA and Department of Health and Human Services (HHS).

Date and Time: The meeting will be held on June 28, 2005, from 8:30 a.m. to 4 p.m.

Addresses: Electronic copies of the documents for public review can be viewed at the Pediatric Advisory Committee (PAC) Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2005 and scroll down to Pediatric Ethics Subcommittee meeting for 06–28–05.) Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments.* Select Docket No. 2005N–0184, entitled ''Surfactant IRB Referral'' and follow the prompts to submit your statement. Written comments should be submitted to Division of Dockets Management (HFA–

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please submit comments by June 7, 2005. Received comments may be viewed on the FDA Web site at: *http://www.fda.gov/ohrms/dockets*, or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Location: U.S. Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD.

Contact Person: Jan N. Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14C–06), Rockville, MD 20857, 301–827–6687, or by e-mail: *jjohannessen@fda.gov*. Please call the FDA Advisory Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001, for up-to-date information on this meeting.

Agenda: The Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will meet to discuss a referral by an Institutional Review Board (IRB) of a proposed clinical investigation that involves both an FDA regulated product and research involving children as subjects that may be supported by HHS. The proposed clinical investigation is entitled ''Precursor Preference in Surfactant Synthesis of Newborns.'' Because the proposed clinical investigation would be regulated by FDA, and conducted or supported by HHS; both FDA and the Office for Human Research Protections, HHS, will participate in the meeting.

After presentation of an overview of the IRB referral process, background information on surfactant synthesis, an overview of the protocol and the referring IRB's deliberations on the protocol, and a summary of public comments received concerning whether the protocol should proceed, the subcommittee will discuss the proposed protocol and develop a recommendation regarding whether the protocol should proceed. The subcommittee's recommendation will then be presented to the FDA Pediatric Advisory Committee on June 29, 2005; the announcement of the June 29 and June 30, 2005, meeting can be found elsewhere in this issue of the **Federal Register**.

Also elsewhere in this issue of the **Federal Register** is a notice announcing a public comment period concerning whether the proposed clinical investigation should proceed. Information regarding submitting comments during that period is contained in that notice.

The background materials for the subcommittee meeting will be made publicly available no later than one day before the meeting and will be posted under the PAC Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Pediatric Advisory Committee, Pediatric Ethics Subcommittee meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by June 17, 2005. 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 by June 17, 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 notify Jan Johannessen at least 7 days prior to the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 19, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–10437 Filed 5–24–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0183]

Draft Guidance for Industry on Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency.'' This guidance is being issued to assist sponsors in developing and submitting nonclinical and clinical virology data, which are important to support clinical trials of antiviral agents. Nonclinical and clinical virology reports are essential components in the review of investigational antiviral drugs. The information in this guidance will facilitate the development of antiviral drug products.

DATES: Submit written or electronic comments on the draft guidance by July 25, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lisa K. Naeger, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20857, 301–827–2330; or Julian O'Rear, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency.'' The purpose of this guidance is to assist sponsors in the development of antiviral drug products and to serve as a starting point for understanding the nonclinical and clinical virology data important to support clinical trials of antiviral agents. This guidance focuses on nonclinical and clinical virology studies, which are essential components in the review of