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

investigational antiviral drugs. Topics in this guidance include studies defining the mechanism of action, establishing specific antiviral activity of the investigative drug, providing data on the development of viral resistance to the investigational drug, and providing data identifying cross-resistance to approved drugs having the same target.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on antiviral drug development; conducting virology studies and submitting the data to the agency. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0014 (until January 31, 2006).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10431 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]

Solicitation of Public Review and Comment on Research Protocol: Precursor Preference in Surfactant Synthesis of Newborns

AGENCY: Office of Public Health and Science and Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services (HHS), and the Food and Drug Administration (FDA), are soliciting public review and comment on a proposed research protocol entitled ''Precursor Preference in Surfactant Synthesis of Newborns.'' The proposed research would be conducted at the St. Louis Children's Hospital and supported by the National Heart, Lung and Blood Institute. Public review and comment are solicited regarding the proposed research protocol under the requirements of HHS and FDA regulations.

DATES: To be considered, written or electronic comments on the proposed research must be received on or before 4:30 p.m. on June 17, 2005.

ADDRESSES: Electronic copies of the documents for public review can be viewed at the Pediatric Advisory Committee Docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Pediatric Ethics Subcommittee meetings.) Submit written comments to the Division of Dockets Management (HFA–305), Docket No. 2005N–0184, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be viewed on FDA's Web site at *http://www.fda.gov/ohrms/dockets/dockets/05n0184/05n0184.htm*, or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Kevin Prohaska, Office for Human Research Protections, The Tower Building, 1101 Wootton Pkwy., suite 200, Rockville, MD 20852, 301–496–7005, FAX: 301- 402–2071, e-mail: *kprohask@osophs.dhhs.gov*; or 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*.

SUPPLEMENTARY INFORMATION: All studies conducted or supported by HHS that are not otherwise exempt and that propose to involve children as subjects require Institutional Review Board (IRB) review in accordance with the provisions of HHS regulations for the protection of human subjects in 45 CFR part 46, subpart D. Under FDA's interim final rule effective April 30, 2001, FDA adopted similar regulations in part 50, subpart D (21 CFR part 50, subpart D) to provide safeguards for children enrolled in clinical investigations of FDA-regulated products. Because the proposed research, ''Precursor Preference in Surfactant Synthesis of Newborns,'' would be supported by NIH, a component of HHS, and would be regulated by FDA, both HHS and FDA regulations apply to this proposed research.

Under HHS regulations in 45 CFR 46.407, and FDA regulations in § 50.54, if an IRB reviewing a protocol to be conducted or supported by HHS for a clinical investigation regulated by FDA does not believe that the proposed research involving children as subjects meets the requirements of HHS regulations in 45 CFR 46.404, 46.405, or 46.406, and FDA regulations in §§ 50.51, 50.52, or 50.53, the research may proceed only if the following conditions are met: (1) IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (2) the Secretary (HHS) and the Commissioner (FDA), after consultation with experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following opportunity for public review and comment, determine either: (a) That the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406 under HHS regulations, and §§ 50.51, 50.52, or 50.53 under FDA regulations, or (b) that the following conditions are met: (i) The research or clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research or clinical investigation will be conducted in accordance with sound ethical principles; and (iii) adequate provisions are made for soliciting the assent of