Atlanta, GA 30341–3724. Telephone: (770) 488–7968. E-mail address: *bas4@cdc.gov.*

Dated: March 27, 2003.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–8062 Filed 4–2–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; 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: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

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 April 22, 2003, from 8:30 a.m. to 5 p.m. and April 23, 2003, from 8:30 a.m. to 12:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5600 Fishers Lane, Rockville, MD.

Contact Person: Kathleen Reedy, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827–7001, e-mail: REEDYK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 22, 2003, the subcommittee will discuss: (1) Quantitative risk-benefit analysis using exposure-response for determining dose adjustment for special populations; and (2) pediatric population pharmacokinetics study design template and analyses of the FDA pediatric database. On April 23, 2003, the subcommittee will discuss: (1) Pharmacogenetics: improvement of existing drug treatments, and (2) drug interactions: metabolism and transport-based.

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 April 15, 2003. Oral presentations from the public will be scheduled between approximately 12:45 p.m. and 1:15 p.m. on April 22, 2003, and 11:30 a.m. to 12 noon on April 23, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 15, 2003, 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 Kathleen Reedy at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: March 25, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–8011 Filed 4–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1738]

Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action; 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 ''Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action.'' This draft document provides recommendations to applicants planning product quality studies to document bioavailability (BA) or bioequivalence (BE) in support of new drug applications (NDAs), or abbreviated new drug applications (ANDAs) for locally acting drugs in nasal aerosols (metered-dose inhalers) and nasal sprays (metered-dose spray pumps). The draft guidance was originally issued for comment on June 24, 1999. Since many substantive changes have been made to the guidance, it is being reissued for comment as a level 1 draft guidance.

DATES: Submit written or electronic comments on the draft guidance by July 2, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry 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 Dockets Management Branch (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: Wallace P. Adams, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5651.

SUPPLEMENTARY INFORMATION: