Specifically, Mr. Leonhard (1) fabricated experimental records and falsely represented them to his supervisor as being results obtained from multiple electrophysiological screening sessions conducted on eight animals; and (2) fabricated two surgical records as evidence of experimental preparations (implantation of indwelling electrodes) on two animals, which in fact had not been done. The experimental records did not appear in any publications.

Mr. Leonhard has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the three (3) year period beginning September 8, 1997:

(1) To exclude himself from serving in any advisory capacity to the Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) That any institution that submits an application for PHS support for a research project on which Mr. Leonhard's participation is proposed or which uses him in any capacity on PHS supported research or that submits a report of PHS-funded research in which he is involved must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Mr. Leonhard's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

No scientific publications were required to be corrected as part of this Agreement.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 97–24808 Filed 9–17–97; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Biological Response Modifiers Advisory Committee.

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

Date and Time: The meeting will be held on October 17, 1997, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: During the morning session, the committee will discuss Zenapax®, (daclixiamab, a humanized monoclonal antibody directed against the human interleukin 2 receptor), Hoffmann-La Roche. An indication is sought for the prophylaxis of acute organ rejection as part of an immunosuppressive regimen for patients receiving cadaveric kidney transplants. During the afternoon session, the committee will discuss Intron-A®, (recombinant human interferon, interferon alfa–2b), Schering-Plough Corp. An indication is sought for the treatment of patients with high-tumor burden, follicular non-Hodgkin's lymphoma, in conjunction with combination chemotherapy.

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 October 10, 1997. Oral presentations from the public will be scheduled between approximately 8 a.m. to 8:30 a.m., and 1 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 10, 1997, 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.

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

Dated: September 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–24849 Filed 9–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Cardiovascular and Renal Drugs Advisory Committee.

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

Date and Time: The meeting will be held on October 23, 1997, 8:30 a.m. to 5:30 p.m., and October 24, 1997, 9 a.m. to 4 p.m.

Location: National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Parking in the Clinical Center visitor area is reserved for Clinical Center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8 minutes during rush hour and every 15 minutes at other times.

Contact Person: Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), 419–259–6211, or Danyiel D'Antonio (HFD–21), 301–443–5455, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 23, 1997, the committee will discuss basic statistical considerations for the evaluation of active control clinical trials, and new drug application (NDA) 20–845, inhaled nitric oxide (Ohmeda Pharmaceutical Products Division, Inc.), for treatment of primary pulmonary hypertension of the newborn. On October 24, 1997, the committee will discuss NDA 20–839, Plavix™ (clopidogrel bisulfate, Sanofi

Pharmaceuticals, Inc.), for prevention of vascular ischemic events in patients with a history of symptomatic atherosclerotic disease.

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 October 9, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on October 23, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 9, 1997, 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.

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

Dated: September 10, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–24848 Filed 9–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 97D–0383]

Draft Guidance for Industry on Population Pharmacokinetics; 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 ''Population Pharmacokinetics.'' This draft guidance is intended to provide recommendations regarding the use of population pharmacokinetics in the drug development process. It summarizes scientific and regulatory issues that should be addressed during the conduct of population pharmacokinetic studies/analyses.

DATES: Written comments may be submitted on the draft guidance document by November 17, 1997. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry entitled ''Population Pharmacokinetics'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Request and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Shiew-Mei Huang, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5671, FAX 301–594–2503.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Population Pharmacokinetics.'' Population pharmacokinetics is the study of the sources and correlates of variability in plasma drug concentrations between individuals, representative of those in whom the drug will be used clinically when clinically relevant dosage regimens are administered. Certain pathophysiological features of patients can regularly alter dose-concentration relationships. For example, renal failure usually causes steady state drug concentrations to be greater than those of patients with normal renal function receiving the same dosage of a drug eliminated mostly by the kidney. Population pharmacokinetics seeks to discover which measurable pathophysiologic factors cause changes in the dose-concentration relationship and to what degree so that appropriate dosage can be recommended.

This draft guidance presents a comprehensive overview of population methods, including when to perform a population study/analysis; how to design and execute population pharmacokinetic studies; how to handle and analyze population pharmacokinetic data; how to perform internal and external validation of population pharmacokinetic models; and how to provide the appropriate documentation for population pharmacokinetic reports intended for submission to the FDA.

This draft guidance represents the agency's current thinking on population pharmacokinetics. 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 requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments 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. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this draft guidance is available on the Internet at http://www.fda.gov/cder/guidance/index.htm.

Dated: September 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24733 Filed 9–12–97; 4:34 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–201]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently