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