Oncologic Drugs Advisory Committee

Date, time, and place. February 14, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 4:30 p.m.; Adele S. Seifried, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of cancer.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 10, 1995, 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 required to make their comments.

Open committee discussion. The committee will discuss in the order listed: (1) NDA 50–718, Dox-SL (pegylated liposomal doxorubicin hydrochloride, Liposome Technology, Inc.) for AIDS-related Kaposi's Sarcoma in patients who have failed prior systemic combination chemotherapy either due to progression of disease or unacceptable toxicity; and (2) NDA 20–515, Zoladex® (goserelin acetate implant, Zeneca Pharmaceuticals Group) for palliative treatment of advanced breast cancer in pre- and perimenopausal women.

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. February 23 and 24, 1995, 8:30 a.m., 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.

Type of meeting and contact person. Open public hearing, February 23, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5:30 p.m.; open committee discussion, February 24, 1995, 8:30 a.m. to 5:30 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419-259-6211, Valerie M. Mealy, Advisors and Consultants Staff, 301-443-4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Cardiovascular and Renal Drugs Advisory Committee, code 12533.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 6, 1995, 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 required to make their comments.

Open committee discussion. On February 23, 1995, the committee will discuss: (1) NDA 09–218, S–76, Dupont Merck, Coumadin® (warfarin), for prevention of death, recurrent myocardial infarction, and thromboembolic events, such as stroke after myocardial infarction; and (2) NDA 20–444, Burroughs Wellcome Co., Flolan® (epoprostenol), for treatment of primary pulmonary hypertension. On February 24, 1995, the committee will discuss antianginal guidelines.

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. February 23 and 24, 1995, 8:30 a.m., Holiday Inn Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, February 23, 1995, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open public hearing, February 24, 1995, 8:30 a.m. to 9 a.m., unless public participation does not last that long;

open committee discussion, 9 a.m. to 4 p.m.; Kathleen R. Reedy, Center for Drug Evaluation and Research, Advisors and Consultants Staff, HFD–9, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, FAX (301–443–0699), or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Endocrinologic and Metabolic Drugs Advisory Committee, code 12536.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 16, 1995, 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 required to make their comments.

Open committee discussion. On February 23, 1995, the committee will hear presentations and discuss data submitted regarding the safety and efficacy of sermorelin acetate, NDA 20–443 (Geref®, Serono), for a growth hormone insufficiency indication. On February 24, 1995, the committee will discuss nilutamide, NDA 20–169 (Anandron®, Roussel Uclaf), for a prostate cancer indication.

Board of Tea Experts

Date, time, and place. February 27 and 28, 1995, 10 a.m., New York Regional Laboratory, rm. 700, 850 Third Ave., Brooklyn, NY.

Type of meeting and contact person. Open public hearing, February 27, 1995, 10 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 4:30 p.m.; open committee discussion, February 28, 1995, 10 a.m. to 4:30 p.m.; Faith F. Lim, New York Regional Laboratory, Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 718–965–5730, or FDA Advisory Committee Information Hotline, 1–800–8138 (301–443–0572 in the Washington, DC area), Board of Tea Experts, code 12601.

General function of the board. The board advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea