Causal research to identify and investigate the relationships between hazardous working conditions and associated occupational disease and injury; (b) the nature and magnitude of special risk factors experienced by older and/or minority workers; (c) methods research to develop more sensitive means of evaluating hazards at work sites; and (d) evaluations of the effectiveness of new approaches or combinations of techniques such as control technologies and personal protective equipment, work organization changes, worker participation programs, and training in reducing or eliminating traumatic injuries and work-related musculoskeletal injuries.

Request For Application Number 98030 entitled, ''Occupational Radiation and Energy-Related Health Research Grants,'' which pertains to research endeavors outlined as follows:

(a) Research to identify and investigate the relationships between health outcomes and occupational exposure to radiation and other hazardous agents; (b) epidemiological methods research relevant to energy-related occupational health research; and (c) research related to assessing occupational exposures. The focus of proposed research should reflect the following topical areas, emphasizing field research: (1) Retrospective exposure assessment; (2) radiation measurement issues; (3) non-cancer morbidity and mortality outcomes; (4) meta-analysis and combined analysis methodologies; (5) uncertainty analysis; (6) effects of measurement error on risk estimates; (7) studies of current workers; and (8) risk communication and worker outreach.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals as outlined above which will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses. It is anticipated that research funded will promote these program goals.

Matters To Be Discussed: The meeting will convene in open session from 8–8:30 a.m. on August 5, 1998, to address matters related to the conduct of Study Section business. The remainder of the meeting will proceed in closed sessions. The purpose of the closed sessions is for the Task Group to consider safety and occupational health grant applications related to the cited solicitation. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone 304/285–5979.

Dated: May 7, 1998.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–12825 Filed 5–13–98; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs 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: Oncologic 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 June 1, 1998, 8:30 a.m. to 5:30 p.m., and June 2, 1998, 8 a.m. to 5:30 p.m.

Location: Gaithersburg Hilton, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4090, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 1, 1998, the committee will discuss: (1) New drug application (NDA) 20–892 AD 32 (valrubicin 40 milligrams/milliliter), Anthra Pharmaceuticals, Inc., indicated for the treatment of refractory carcinoma *in situ* of the urinary bladder; and (2) NDA supplement 20–449/S–005 Taxotere® (docetaxel) for injection concentrate, Rhone-Polenc Rorer Pharmaceuticals, Inc., indicated for the treatment of patients with locally advanced or metastatic breast cancer who have failed previous chemotherapy. On June 2, 1998, the committee will discuss: (1) Biologics license application (BLA) 97–1325 ONTAK™ (denileukin diftitox) injection (DAB_{389} IL–2), Seragen, Inc., indicated for the treatment of cutaneous T-cell lymphoma (CTCL); and (2) NDA supplement 20–671/S–004 Hycamtin® (topotecan HCl) for injection, SmithKline Beecham Pharmaceuticals, indicated for the second-line treatment of patients with small cell lung cancer.

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 May 22, 1998. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., on June 1, 1998, and between approximately 8:15 a.m. and 8:45 a.m., on June 2, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 15, 1998, 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: May 7, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–12756 Filed 5–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0284]

Guidance for Industry on Classifying Resubmissions in Response to Action Letters; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Classifying Resubmissions in Response to Action Letters.'' This guidance explains how the agency will classify resubmissions of new drug applications (NDA's) and license applications (LA's) and specifies the agency's response timeframes. The guidance also recommends procedures for making resubmissions.

DATES: Written comments may be submitted on the guidance by August 12, 1998. General comments on the agency guidance documents are welcome at any time.