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.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the address below.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–002), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Classifying Resubmissions in Response to Action Letters.'' In the Prescription Drug User Fee Act of 1992 (PDUFA), FDA committed to certain user fee performance goals, including the goal of responding to an applicant's resubmission of an original NDA or LA in 6 months or less. In her letter to Congress regarding the reauthorization of PDUFA in November 1997 as part of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Secretary of Health and Human Services committed FDA to recognizing two classes of resubmissions: Class 1 and Class 2. This guidance describes the classification of resubmissions as Class 1 or Class 2 based on the information submitted by the applicant in response to the action letter. In addition, the guidance specifies the percentages of resubmissions in each class that will be reviewed and acted upon within a certain time period from the date the resubmission is received by FDA, based on the fiscal year in which the resubmission is received.

This guidance is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance is issued as a Level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on classifying resubmissions in response to action letters. 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 requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the 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 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.

Dated: May 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12830 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–0282]

Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds; 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 ''Submitting and Reviewing Complete Responses to Clinical Holds.'' This guidance describes how to submit a complete response if an investigational new drug application is placed on clinical hold.

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

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm; or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD. 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the addresses that follow.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–002), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400; or

Robert A. Yetter, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Submitting and Reviewing Complete Responses to Clinical Holds.'' Section 117 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), signed into law by President Clinton on November 21, 1997, provides that a written request that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. In addition, the agency committed to user fee performance goals incorporating the same response time. This guidance describes how sponsors should submit responses to clinical holds so that they may be identified as complete responses and the agency can track the time to response.

This guidance document is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance for industry is a Level 1 guidance consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on submitting complete responses to clinical holds. 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 requirements of the applicable statute, regulations, or both.

The guidance and comments received in the Dockets Management Branch (address above) are available for public examination between 9 a.m. and 4 p.m., Monday through Friday.