not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.) Please do not send applications to the CSR at NIH. Any application sent to NIH that is then forwarded to FDA and received after the applicable due date will be judged nonresponsive and returned to the applicant. Applications must be submitted via mail or hand delivered as stated above. FDA is unable to receive applications electronically.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/01). Applications from State and local governments may be sent on Form PHS 5161–1 (Rev. 7/00) or Form PHS 398 (Rev. 5/01). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed except for the receipt dates and the mailing label address. The face page of the application should reflect the request for applications number RFA–FDA–OPD–2003. The title of the proposed study should include the name of the product and the disease/disorder to be studied and the IND/IDE number. The format for all following pages of the application should be single-spaced and single-sided. FDA does not adhere to the page limits or the type size and line spacing requirements imposed by NIH on its applications.

Applicants have the option of omitting from the application copies (not the original) specific salary rates or amounts for individuals specified in the application budget and Social Security numbers if otherwise required for individuals. The copies may include summary salary information.

Data and information included in the application will generally not be publicly available prior to the funding of the application. Data and information included in the application, if identified by the applicant as trade secret or confidential commercial information, will be given confidential treatment to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (including inter alia 21 CFR 20.61) even after funding has been granted. Information collection requirements requested on Form PHS 398 (Rev. 5/01) have been sent by the PHS to the Office of Management and Budget (OMB) and have been approved and assigned OMB control number 0925–0001. The requirements requested on Form PHS 5161–1 (Rev. 7/00) were approved and assigned OMB control number 0348–0043.

Applicants should provide a summary of any meetings or discussions about the clinical study that have occurred with FDA reviewing division staff as an appendix to the application.

Dated: August 21, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–21736 Filed 8–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products 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: Blood Products Advisory Committee.

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

Date and Time: The meeting will be held on September 12, 2002, from 8 a.m. to 5:30 p.m.

Location: Hilton Silver Spring Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD 20910.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 12, 2002, the following committee updates are tentatively scheduled: (1) Consideration of the Clinical Laboratory Improvement Act (CLIA) waivers for rapid human immunodeficiency virus (HIV) tests; (2) implementation of HIV, type 1/hepatitis C virus nucleic acid testing algorithm; (3) summary of Public Health Service Advisory Committee on Blood Safety and Availability meeting held on September 5, 2002; (4) summary of the workshop on pathogen inactivation held on August 7 and 8, 2002; and (5) blood establishment registration—electronic submissions. In the morning, the committee will hear discussion and provide recommendations on the topic of self-administration of the uniform donor history questionnaire: first time donors. In the afternoon, the committee will hear an informational presentation on testing for Chagas disease, and a presentation on window period for HIV cases and current estimates of residual risk.

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 August 30, 2002. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m., and 3:45 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 30, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Linda A. Smallwood or Pearline K. Muckelvene at 301–827–1281 at least 7 days in advance of the meeting.

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

Dated: August 20, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–21734 Filed 8–26–02; 8:45 am]

BILLING CODE 4160–01–S

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's regulatory issues.

Date and Time: The meeting will be held on September 24, 2002, from 8:30 a.m. to 1:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, 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, 301–827–7001, e-mail: SomersK@cder.fda.gov, 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 September 24, 2002, the committee will discuss new drug application (NDA) 21–399, IRESSAr (gefitinib), AstraZeneca Pharmaceuticals LP, indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer who have previously received platinum-based 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 September 16, 2002. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. on September 24, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 16, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Templeton-Somers at least 7 days in advance of the meeting.

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

Dated: August 20, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–21737 Filed 8–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0320]

Draft Guidance for Industry and Clinical Investigators on the Use of Clinical Holds Following Clinical Investigator Misconduct; 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 and clinical investigators entitled ''The Use of Clinical Holds Following Clinical Investigator Misconduct.'' This draft guidance provides information on FDA's use of its authority to impose a clinical hold on a study if FDA finds that a clinical investigator conducting the study has committed serious violations of our regulations pertaining to clinical trials involving human drug or biological products or has submitted false information to FDA or to the study's sponsor in any report. The draft guidance is intended to inform interested persons of the circumstances in which we may impose a clinical hold following the discovery of a clinical investigator's misconduct and the steps we might take to protect human subjects from investigator misconduct.

DATES: Submit written or electronic comments on the draft guidance by November 25, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Rachel Behrman, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758; or

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and clinical investigators entitled ''The Use of Clinical Holds Following Clinical Investigator Misconduct.'' The draft guidance provides information on our authority to impose a clinical hold on a study if we find that a clinical investigator conducting the study has committed serious violations of our regulations pertaining to clinical trials involving human drug or biological products or has submitted false information to us or to the study's sponsor in any report. The draft guidance is intended to inform interested persons of the circumstances in which we may impose a clinical hold following the discovery of a clinical investigator's misconduct and the steps we might take to protect human subjects from investigator misconduct.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the use of clinical holds to protect human subjects following clinical investigator misconduct in a clinical trial of a human drug or biological product. It does not create or confer any rights for or on any person and does not operate to bind us or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes