

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 Pearlina 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.*

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**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.