42 CFR	OMB Control Nos.
489.66, 489.67	0938–0713
489.102	0938–0610
491.1–.11	0938–0074
491.3, 491.8	0938–0792
491.9	0938–0334
491.11	0938–0792
493.1–.2001	0938–0151, 0544, 0581, 0599, 0612, 0650 & 0653
493.551–.557	0938–0686
493.1269–.1285	0938–0170
493.1840	0938–0655
498.40–.95.	0938–0486 & 0567
1003.100, 1003.101, 1003.103.	0938–0700
1004.40, 1004.50, 1004.60, 1004.70.	0938–0444

45 CFR	OMB. Control Nos
5b	0938–0734
146	0938–0702
146.121	0938–0819
146.141	0938–0827
148	0938–0703 & 0797
162	0938–0866

Dated: August 20, 2002.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 02–21711 Filed 8–26–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0007]

Agency Information Collection Activities; Announcement of OMB Approval; CGMP Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''CGMP Regulations for Finished Pharmaceuticals'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 2002 (67 FR 34939), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0139. This approval expires on August 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 21, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–21735 Filed 8–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications (Catalog of Federal Domestic Assistance No. 93.103)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes to its Office of Orphan Products Development (OPD) grant program for fiscal year (FY) 2003. This announcement supercedes the previous announcement of this program, which was published in the **Federal Register** on August 27, 2001.

DATES: The application receipt dates are October 16, 2002, and April 2, 2003.

ADDRESSES: Application requests and completed applications should be submitted to Maura Stephanos, Grants Management Specialist, Grants Management Staff, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183, FAX 301–827–7101, e-mail: mstepha1@oc.fda.gov. Applications that are hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857. Applications may also be obtained from the OPD on the Internet at http://www.fda.gov/orphan or at http://grants.nih.gov/grants/funding/phs398/phs398.html. Note: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management issues of this notice: Maura Stephanos (see **ADDRESSES**).

Regarding the programmatic issues of this notice: Debra Y. Lewis, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 15A–08, Rockville, MD 20857, 301–827–3666, FAX 301–827–0017, e-mail: dlewis@oc.fda.gov.

SUPPLEMENTARY INFORMATION: All studies of new drug and biological products must be conducted under the FDA's investigational new drug (IND) procedures and studies of medical devices must be conducted under the investigational device exemption (IDE) procedures. Studies of approved products to evaluate new orphan indications are acceptable; however, these must also be conducted under an IND or IDE to support a change in labeling. The study protocol proposed in the grant application must be under an active IND or IDE (not on clinical hold) to qualify the application for scientific and technical review. (See Program Review Criteria for important information about the IND/IDE status of products to be studied under these grants.)

Except for medical foods that do not need premarket approval, FDA will only consider awarding grants to support premarket clinical studies to find out whether the products are safe and effective for approval under section 301 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*) or under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262).

FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act. FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103. The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

PHS's policy is that applicants for PHS clinical research grants should include minorities and women in study populations so research findings can be of benefit to all people at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy applies to research subjects of all ages. If women or minorities are excluded or poorly represented in clinical research, the applicant should provide a clear and compelling rationale that shows inclusion is inappropriate.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national effort designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, vols. I and II, for $70 ($87.50 foreign) S/N 017–000–00550–9, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD–ROM format, S/N 017–001–00549–5 for $19 ($23.50 foreign) as well as on the Internet at http://health.gov/healthypeople/. Internet viewers should proceed to ''Publications.''

I. Program Research Goals

OPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and foods for medical purposes that are indicated for a rare disease or condition (that is, one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostic tests and vaccines will qualify only if the U.S. population of intended use is fewer than 200,000 people a year.

The goal of FDA's OPD grant program is the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the product will improve the existing therapy. FDA provides grants for clinical studies that will either result in or substantially contribute to market approval of these products. Applicants should keep this goal in mind and must include an explanation in the application's ''Background and Significance'' section of how their proposed study will either help gain product approval or provide essential data needed for product development. All funded studies are subject to the requirements of the act and regulations issued under it.

II. Award Amounts

FDA is announcing the expected availability of FY 2003 funds for awarding grants to support clinical studies on the safety and effectiveness of products (drugs, biologics, and devices) for rare diseases or conditions (that is, with a prevalence, not incidence, of fewer than 200,000 people in the United States).

Of the estimated FY 2003 funding ($13.3 million), approximately $9.3 million will fund noncompeting continuation awards, and approximately $4 million will fund 12 to 15 new awards. In the first part of the funding cycle, approximately $1 million will be awarded to successful applications received by the October 16, 2002, due date (with the award starting after March 1, 2003). All applications recommended for approval that are not funded in the first part of the cycle will remain in competition for the second part of the funding cycle with applications received by the April 2, 2003, due date. The expected start date for these awards will be September 30, 2003. Applications submitted for the first due date may be withdrawn and resubmitted for the second due date.

Any phase (1, 2, or 3) clinical trial is eligible for up to $150,000 in direct costs a year, plus applicable indirect costs, for up to 3 years. Phase 2 and 3 clinical trials are also eligible for up to $300,000 in direct costs a year, plus applicable indirect costs, for up to 3 years. Study proposals for the smaller grants ($150,000) may be for phase 1, 2, or 3 clinical trials. Study proposals for the larger grants ($300,000) must be continuing in phase 2 or phase 3 of investigation. Phase 2 trials include controlled clinical studies conducted to evaluate the effectiveness of the product for a particular indication in patients with the disease or condition and to determine the common or short-term side effects and risks associated with it. Phase 3 trials gather more information about effectiveness and safety that is necessary to evaluate the overall risk-benefit ratio of the product and to provide an acceptable basis for product labeling. Budgets for all years of requested support may not exceed the $150,000 or $300,000 direct cost limit, whichever is applicable.

III. Human Subject Protection and Informed Consent

A. Protection of Human Research Subjects

All institutions engaged in human subject research supported by the Department of Health and Human Services (DHHS) must file an ''assurance'' of protection for human subjects with the Office for Human Research Protection (OHRP) (45 CFR part 46). Applicants are advised to visit the OHRP Internet site at http://ohrp.osophs.dhhs.gov/ for guidance on human subjects issues. The requirement to file an assurance includes both ''awardee'' and collaborating ''performance site'' institutions. Awardee institutions are automatically considered to be engaged in human subject research whenever they receive a direct DHHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the awardee institution bears the ultimate responsibility for protecting human subjects under the award. The awardee institution is also responsible for ensuring that all collaborating performance site institutions engaged in the research hold an approved assurance prior to their initiation of the research. No awardee or performance site institution may spend funds on human subject research or enroll subjects without the approved and applicable assurance(s) on file with OHRP.

Applicants must also provide certification of Institutional Review Board (IRB) review and approval for every site taking part in the study. This documentation need not be on file with the FDA Grants Management Office prior to the award, but must be on file before research can begin at a site.

Applicants should review the section on human subjects in the application instructions entitled ''I. Preparing Your Application, Section C. Specific Instructions, Item 4, Human Subjects'' for further information.

B. Key Personnel Human Subject Protection Education

The awardee institution should ensure that all key personnel receive appropriate training in their human subject protection responsibilities. Key personnel include all principal investigators, co-investigators, and performance site investigators responsible for the design and conduct of the study. Within 30 days of award, the principal investigator should provide a letter which includes the names of the key personnel, the title of

the human subjects protection education program completed by each named personnel, and a one-sentence description of the program. This letter should be signed by the principal investigator and co-signed by an institution official and sent to the Grants Management Office. Neither DHHS, FDA, or OPD prescribe or endorse any specific education programs. Many institutions have already developed educational programs on the protection of research subjects and have made participation in such programs a requirement for their investigators. Other sources of appropriate instruction might include the online tutorials offered by the Office of Human Subjects Research, NIH at http://ohsr.od.nih.gov/ and by OHRP at http://ohrp.osophs.dhhs.gov/educmat.htm. Also, the University of Rochester has made available its training program for individual investigators. Their manual can be obtained through Centerwatch, Inc., at http://www.centerwatch.com.

C. Informed Consent

Consent forms, assent forms, and any other information given to a subject, should be sent with the grant application (even if such a form is in a draft version). Information given to the subject or his or her representative must be in language the subject or representative can understand. No informed consent, whether verbal or written, may include any language through which the subject or representative waives any of the subject's legal rights, or by which the subject or representative releases or appears to release the investigator, the sponsor, or the institution or its agent from liability. If a study involves both adults and children, separate consent forms should be provided for the adults and the parents or guardians of the children. The applicant is referred to DHHS regulations at 45 CFR 46.116 and 21 CFR 50.25 for details regarding the (required) elements of informed consent.

IV. Reporting Requirements

The original and two copies of the annual Financial Status Report (FSR) (SF–269) must be sent to FDA's grants management officer within 90 days of the budget period end date of the grant. Failure to file the FSR in a timely fashion will be grounds for suspension or termination of the grant. For continuing grants, an annual program progress report is also required. The noncompeting continuation application (PHS 2590) will be considered the annual program progress report. Also, all new and continuing grants must comply with all regulatory requirements necessary to keep active status of their IND/IDE. Failure to meet regulatory requirements will be grounds for suspension or termination of the grant.

The program project officer will monitor grantees quarterly and will prepare written reports. The monitoring may be in the form of telephone conversations or e-mail between the project officer/grants management specialist and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these reports will be recorded in the official grant file and may be available to the grantee on request consistent with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions, which state that future funding of the study will depend on recommendations from the OPD project officer. The scope of the recommendations will confirm that: (1) There has been acceptable progress toward enrollment, based on specific circumstances of the study; (2) there is an adequate supply of the product/device; and (3) there is continued compliance with all FDA regulatory requirements for the trial.

The grantee must file a final program progress report, FSR and invention statement within 90 days after the end date of the project period as noted on the notice of grant award.

V. Mechanism of Support

A. Award Instrument

Support will be in the form of a grant. All awards will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program. The NIH modular grant program does not apply to this FDA grant program. All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the act (21 U.S.C. 355, 360b, and 360e), section 351 of the PHS Act (42 U.S.C. 262), and regulations issued under any of these sections.

B. Eligibility

The grants are available to any foreign or domestic, public or private nonprofit entity (including state and local units of government) and any foreign or domestic, for-profit entity. For-profit entities must commit to excluding fees or profit in their request for support to receive grant awards. Organizations described in section 501(c)4 of the Internal Revenue Code of 1968 that lobby are not eligible to receive grant awards.

C. Length of Support

The length of support will depend on the nature of the study. For those studies with an expected duration of more than 1 year, a second or third year of noncompetitive continuation of support will depend on: (1) Performance during the preceding year, (2) Federal funds availability, and (3) compliance with regulatory requirements of the IND/IDE.

D. Funding Plan

The number of studies funded will depend on the quality of the applications received and the availability of Federal funds to support the projects. Resources for this program are limited. Therefore, if two applications propose duplicative or similar studies, FDA may support only the study with the better score. Funds may be requested in the budget to travel to FDA for meetings with OPD or reviewing division staff about the progress of product development.

Before an award will be made, the OPD will confirm the active status of the protocol under the IND/IDE. If the protocol is under FDA clinical hold for any reason, no award will be made. Also, if the IND/IDE for the proposed study is not active and in regulatory compliance, no award will be made. Documentation of IRB approvals for all performance sites must be on file with the FDA Grants Management Office before research can begin at that site. This grant program does not require the applicant to match or share in the project costs if an award is made.

VI. Review Procedures and Criteria

A. Review Procedures

FDA's grants management and program staff will review all applications sent in response to this notice. To be responsive, an application must: (1) Be received by the specified due date; (2) be submitted in accordance with sections V.B ''Eligibility,'' VII ''Submission Requirements,'' and VIII.A ''Submission Instructions'' of this notice; (3) not exceed the recommended funding amount stated in section II ''Award Amounts'' of this document; (4) be in compliance with the following section VI.B '' Program Review Criteria;'' and (5) bear the original signatures of both the principal investigator and the Institution's/Organization's Authorized Official. Applications found to be nonresponsive

will be returned to the applicant without further consideration (unreviewed). Applicants are strongly encouraged to contact FDA to resolve any questions about criteria before submitting their application. Please direct all questions of a technical or scientific nature to the OPD program staff and all questions of an administrative or financial nature to the grants management staff (see **ADDRESSES**).

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Consultation with the proper FDA review division may also occur during this phase of the review to determine whether the proposed study will provide acceptable data that could contribute to product approval. Responsive applications will be subject to a second review by a National Advisory Council for concurrence with the recommendations made by the first-level reviewers, and funding decisions will be made by the Commissioner of Food and Drugs.

B. Program Review Criteria

Program review criteria include the following:

1. The application must propose a clinical trial intended to provide safety and/or efficacy data of one therapy for one orphan indication.

2. There must be an explanation in the ''Background and Significance'' section of how the proposed study will either contribute to product approval or provide essential data needed for product development.

3. The prevalence, not incidence, of the population to be served by the product must be fewer than 200,000 individuals in the United States. The applicant should include, in the ''Background and Significance'' section, a detailed explanation supplemented by authoritative references in support of the prevalence figure. Diagnostic tests and vaccines will qualify only if the population of intended use is fewer than 200,000 individuals in the United States per year.

4. The study protocol proposed in the grant application must be under an active IND or IDE (not on clinical hold) to qualify the application for scientific and technical review. Additional IND/IDE information is described below:

- The proposed clinical protocol should be submitted to the FDA IND/IDE reviewing division a minimum of 30 days before the grant application deadline.
- The number assigned to the IND/IDE that includes the proposed study should appear on the face page of the application with the title of the project. The date the subject protocol was submitted to FDA for the IND/IDE review should also be provided.
- Protocols that would otherwise be eligible for an exemption from the IND regulations must be conducted under an active IND to be eligible for funding under this FDA grant program.
- If the sponsor of the IND/IDE is other than the principal investigator listed on the application, a letter from the sponsor permitting access to the IND/IDE must be submitted. Both the name of the principal investigator identified in the application and the study protocol must have been submitted to the IND/IDE.
- Studies of already approved products, evaluating new orphan indications, are also subject to these IND/IDE requirements.
- Only medical foods that do not need premarket approval are exempt from these IND/IDE requirements.

5. The requested budget must be within the limits (either $150,000 in direct costs for each year for up to 3 years for any phase study, or $300,000 in direct costs for each year for up to 3 years for phase 2 or 3 studies) as stated in this notice. Any application received that requests support over the maximum amount allowable for that particular study will be considered nonresponsive.

6. Proposed consent forms, assent forms, and any other information given to a subject, should be included in the grant application (even if they are in a draft version).

7. Evidence that the product to be studied is available to the applicant in the form and quantity needed for the clinical trial must be included in the application. A current letter from the supplier as an appendix will be acceptable.

8. Applicants must follow guidelines named in the PHS 398 (Rev. 5/01) grant application instructions.

C. Scientific/Technical Review Criteria

The ad hoc expert panel will review the application based on the following scientific and technical merit criteria:

1. The soundness of the rationale for the proposed study.

2. The quality and appropriateness of the study design including the rationale for the statistical procedures.

3. The statistical justification for the number of patients chosen for the study, based on the proposed outcome measures and the appropriateness of the statistical procedures for analysis of the results.

4. The adequacy of the evidence that the proposed number of eligible subjects can be recruited in the requested timeframe.

5. The qualifications of the investigator and support staff, and the resources available to them.

6. The adequacy of the justification for the request for financial support.

7. The adequacy of plans for complying with regulations for protection of human subjects.

8. The ability of the applicant to complete the proposed study within its budget and within time limits stated in this RFA.

A score will be assigned based on the above scientific/technical review criteria. The review panel may advise the program staff about the appropriateness of the proposal to the goals of the OPD grant program described in the section I ''Program Research Goals'' of this document.

VII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 5/01) or the original and two copies of PHS 5161–1 (Rev. 7/00) for State and local governments, with three copies of the appendices should be submitted to Maura Stephanos (see **ADDRESSES**). State and local governments may use the PHS 398 (Rev. 5/01) application form in lieu of the PHS 5161–1. The application receipt dates are October 16, 2002, and April 2, 2003. The only material will be accepted after the receipt date is evidence of final IRB approval. The mailing package and item 2 of the application face page should be labeled, ''Response to RFA–FDA–OPD–2003.'' If an application for the same study was submitted in response to a previous RFA but has not yet been funded, an application in response to this notice will be considered a request to withdraw the previous application. Resubmissions are treated as new applications; therefore, the applicant may wish to address the issues presented in the summary statement from the previous review, and include a copy of the summary statement itself as part of the application.

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, from 8 a.m. to 4:30 p.m., Monday through Friday, by the established receipt dates. Applications will be considered received on time if sent or mailed by the receipt dates as shown by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier. Private metered postmarks shall

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.