

granting exemption from Federal preemption.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.1(d)	1	1	1	40	40

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for § 100.1(d) is insignificant because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions; therefore, the agency estimates that one or fewer petitions will be submitted annually. Because § 100.1(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403(A) of the act.

Dated: May 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-13588 Filed 5-29-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Safety and Effectiveness of Products for the Treatment of Naturally Occurring Human Plague (Bubonic, Pneumonic, Meningitic, or Septicemic); Availability of Grants; Request for Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing its Office of Pediatric Drug Development and Program Initiatives (OPDDPI) grant program for fiscal year (FY) 2002. FDA is announcing the expected availability of FY 2002 funds for awarding grants to support clinical trials on the safety and effectiveness of drug products for the treatment of human plague (bubonic, pneumonic, meningitic, or septicemic) caused by

*Yersinia pestis*. This grant program is part of FDA's counter-terrorism efforts.

**DATES:** The application receipt date is July 29, 2002.

**ADDRESSES:** Application forms are available from, and completed applications should be sent to: Rosemary Springer, Grants Management Specialist, Division of Contracts and Procurement Management (HFA-522), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7182, rspringe@oc.fda.gov. Application forms can also be found at [http://www.nih.gov/grants/phs398/forms\\_toc.html](http://www.nih.gov/grants/phs398/forms_toc.html). Please do not send applications to the Center for Scientific Review (CSR), National Institutes of Health (NIH). Applications mailed to CSR and not received by FDA in time for orderly processing will be returned to the applicant without consideration. (Note: completed applications that are hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857.) FDA is unable to receive applications electronically.

#### FOR FURTHER INFORMATION CONTACT:

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

*Regarding the programmatic issues of this notice:* Joanne M. Holmes, Office of Pediatric Drug Development and Program Initiatives (HFD-950), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2350, e-mail: [holmesj@cder.fda.gov](mailto:holmesj@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the expected availability of FY 2002 funds for awarding grants to support clinical trials on the safety and effectiveness of drug products for the treatment of human plague (bubonic, pneumonic, meningitic, or septicemic). Subject to the availability of FY 2002 funds, it is anticipated that \$2.1 million should be available. FDA anticipates making up to three awards each for up to \$700,000 (direct and indirect costs). Funding will be provided one time at the beginning of the project and will

cover both years of the project period. The budget and project periods will coincide for these awards. These awards will start before September 30, 2002.

FDA will support the clinical studies covered by this notice under the authority of section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). 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.

FDA is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national effort to reduce morbidity and mortality and to improve the quality of life. Applicants may obtain a hard copy of the "Healthy People 2010" objectives, vols. I and II, conference edition (B0074) for \$22 per set, by writing to the Office of Disease Prevention and Health Promotion (ODPHP) Communication Support Center (Center), P.O. Box 37366, Washington, DC 20013-7366. Each of the 28 chapters of "Healthy People 2010" is priced at \$2 per copy. Telephone orders can be placed to the Center on 301-468-5690. The Center also sells the complete conference edition in CD-ROM format (B0071) for \$5. This publication is available as well on the Internet at <http://www.health.gov/healthypeople/>. Internet viewers should proceed to "Publications."

PHS 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.

### I. Program Research Goals

OPDDPI has as one of its goals the identification and facilitation of development of drug products that may be used in the treatment of conditions caused by agents released in a terrorist event. These agents can be of a pathogenic, radiological, or chemical nature.

To ensure that the needs of the public health, including special populations, are met, it is necessary to have an array of approved drug products available and labeled to treat such conditions. One approach to facilitating drug product availability is to support clinical research to determine if drug products approved for another indication are safe and effective for use in an indication related to terrorism and to utilize such information to provide appropriate dosing and use information in the label. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued under it.

Although gentamicin is not FDA approved for treatment of pneumonic plague, the Center for Civilian Biodefense Studies Working Group on Civilian Biodefense has recommended it along with streptomycin as a preferred therapy. FDA obtained from the Centers for Disease Control and Prevention (CDC) at Fort Collins, CO, the limited data on all reported U.S. pneumonic plague cases, both primary and secondary, from the 1950s to the present. Because of multiple confounders in this limited population and because no patients received gentamicin alone, no conclusions could be reached to support labeling gentamicin as monotherapy for pneumonic plague. Therefore, the goal of FDA's OPDDPI grant program is the clinical development of products for use in plague (bubonic, pneumonic, meningitic, or septicemic). FDA provides grants for clinical studies that will either result in or substantially contribute to the addition of a plague indication to gentamicin. 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 of this indication or provide essential data needed for product development. The applicant should provide a summary of any meetings or discussions about the clinical study that have occurred to date

with FDA review division staff as an appendix to the application.

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 the act (21 U.S.C. 301 *et seq.*) or under section 351 of the PHS Act (42 U.S.C. 262). All studies of new drug products must be conducted under the FDA's investigational new drug (IND) procedures. Although gentamicin is an approved product, studies of approved products to evaluate new indications must be conducted under an IND to support a change in labeling. (See Program Review Criteria in section V.B of this document for important requirements about IND status of products to be studied under this grant.)

Studies proposed for this grant must be 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 physician labeling.

Applications must propose a controlled clinical trial of gentamicin versus an antibiotic already approved for plague (doxycycline or streptomycin) in the treatment of human plague (bubonic, pneumonic, meningitic, or septicemic). Historical data from untreated patients will be considered as the negative control. A plan to obtain a minimum of 30 plague-confirmed patients per arm is required. The diagnosis of plague should be confirmed by culture and/or serology. The applicant must provide supporting evidence that the product to be studied is available to the applicant in the form and quantity needed for the clinical trial. The applicant must also provide supporting evidence that the patient population has been surveyed and reasonable assurance that the necessary number of eligible patients is available for the study. Funds may be requested in the budget to travel to FDA for meetings with review division staff about the progress of product development.

## II. 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). Some activities carried out by a recipient under this announcement may be governed as well by the FDA Research Involving Human Subjects Committee part 50 (21 CFR part 50) and (21 CFR part 56). Applicants may wish to visit the OHRP Internet site at <http://ohrp.osoph.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 ultimate responsibility for protecting human subjects under the award. The awardee is also responsible for ensuring that all collaborating institutions engaged in the research hold an approved assurance prior to their initiation of the research. No awardee or performance site may spend funds on human subject research or enroll subjects without the approved and applicable assurance(s) on file with OHRP.

Existing assurances, multiple project assurances (MPAs), cooperative project assurances (CPAs), and single project assurances (SPAs), will remain in effect through their current expiration date, or December 31, 2003, whichever comes first. However, OHRP no longer accepts changes to existing MPAs, CPAs, and SPAs. MPA, CPA, and SPA institutions should file a new Federal wide assurance with OHRP if changes are necessary. Applicants must provide certification of Institutional Review Board (IRB) review and approval for every site taking part in the study. However, this documentation need not be on file with the grants management officer, FDA before the award. Applicants should review the section on human subjects in the application kit entitled "Section C. Specific Instructions—Forms, Item 4, Human Subjects" (pp. 7 and 8 of the application kit), for IRB review requirements.

### *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. Within 30 days of award, the principal investigator should provide a letter describing the human subjects protection training for each individual identified as "key personnel" in the proposed research. Key personnel include all principal investigators, coinvestigators, and performance site investigators responsible for the design and conduct of the study. The description of training should be submitted in a letter that includes the names of the key personnel, the title of the 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 cosigned by an institution official and sent to the Grants Management Office. OPDDPI does not prescribe or endorse any specific education programs. Many institutions already have 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. 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.

### *D. Elements of Informed Consent*

The elements of informed consent are stated in the DHHS regulations at 45 CFR 46.116 and § 50.25 as follows:

#### 1. Basic Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject.

(a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

(b) A description of any reasonably foreseeable risks or discomforts to the subject.

(c) A description of any benefits to the subject or to others that may reasonably be expected from the research.

(d) A discussion of proper alternative procedures or courses of treatment, if any, that might be helpful to the subject.

(e) A statement that describes the extent, if any, to which confidentiality of records identifying the subject will be maintained, and that notes the possibility that FDA may inspect the records.

(f) For research involving more than slight risk, an explanation of whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be gained.

(g) An explanation of whom to contact for answers to relevant questions about the research and research subject's rights, and whom to contact if the subject is injured by the research.

(h) A statement that participation is voluntary, that refusal to take part will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may stop participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

#### 2. Other Elements of Informed Consent

When suitable, one or more of the following elements of information shall also be provided to each subject:

(a) A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) that are unforeseeable.

(b) Anticipated circumstances under which the investigator, without regard to the subject's consent, may stop the subject's participation.

(c) Any costs to the subject that may result from participation in the research.

(d) The consequences of a subject's decision to withdraw from the research

and procedures for orderly ending of participation by the subject.

(e) A statement that significant new findings developed during the research that may affect the subject's willingness to continue participation will be provided to the subject.

(f) The estimated number of subjects involved in the study.

The informed consent requirements do not intend to preempt any applicable Federal, State, or local laws that require other information to be disclosed for informed consent to be legally effective. Nothing in the notice intends to limit the authority of a physician to provide emergency medical care as permitted under applicable Federal, State, or local law.

### **III. 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 at two occasions during these projects. The first FSR will be due 15 months after date of award and the final FSR will be due 90 days after the end of the grant. Failure to file the FSR in a timely fashion will be grounds for suspension or termination of the grant. All grants must comply with all regulatory requirements necessary to keep active status of their IND. This includes, but is not limited to, submission of an annual report to the proper regulatory review division within FDA. 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.

In addition to annual reports submitted to the IND according to the requirements under 21 CFR 312.33, 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. Progress reports throughout the project will be required semiannually (every 6 months). These progress reports must be sent to the Grants Management Officer and should include the following cumulative and incremental counts: Patients enrolled; patients who are

culture positive for *Y. pestis*; patients with a positive seroconversion to *Y. pestis*; pneumonic, septicemic, meningitic, and/or bubonic plague cases; patients treated; treatment outcomes; and adverse events (categorized by type and severity).

#### IV. 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 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's 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

These 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 engage in lobbying are not eligible to receive grant awards.

##### C. Length of Support

The length of support will be for 2 years.

##### D. Funding Plan

It is anticipated that three new awards will be funded for up to 2 years each. Before an award will be made, OPDDPI will confirm the active status of the protocol under the IND. If the protocol is under FDA clinical hold for any reason, no award will be made. Also, if the IND for the proposed study is not active and in complete regulatory compliance, no award will be made. Documentation of IRB approvals for all performance sites must be on file with the Grants Management Office, FDA (see **ADDRESSES**), before research can begin at that site.

#### V. Review Procedure and Criteria

##### A. Review Method

Grants management and program staff will first review all applications sent in

response to this request for application (RFA). A responsive application is defined as being in compliance with the program review criteria in section V.B of this document. Applications found to be nonresponsive will be returned to the applicant without further consideration.

##### B. Program Review Criteria

Applicants are strongly encouraged to contact FDA to resolve any questions about criteria before submitting their application. Direct all questions of a technical or scientific nature to the OPDDPI program staff and all questions of an administrative or financial nature to the grants management staff. (See the **FOR FURTHER INFORMATION CONTACT** section). Applications considered nonresponsive will be returned to the applicant unreviewed. Responsiveness criteria include the following:

1. The application must propose a clinical trial intended to provide safety and efficacy data of gentamicin for plague (bubonic, pneumonic, meningitic, or septicemic) compared to either doxycycline or streptomycin. There should be a plan to recruit a minimum of 30 plague confirmed patients per treatment arm. The diagnosis of plague should be confirmed by culture and/or serology.

2. There must be an explanation in the "Background and Significance" section of how the proposed study will either contribute to approval of gentamicin for plague (bubonic, pneumonic, meningitic, or septicemic) or provide essential data needed for product development.

3. The protocol proposed in the grant application must already be under an active IND (not under review or on hold) before the grant application deadline, described as follows:

- (a) The IND with the proposed clinical protocol must be submitted to the FDA IND reviewing division a minimum of 30 days before the grant application deadline. The IND must be in active status, in compliance with all regulatory requirements and cannot have any type of FDA clinical hold placed on it at the time the grant application is submitted.

- (b) The number assigned to the IND that includes the proposed study must appear on the face page of the application with the title of the project.

- (c) The applicant should submit an IND verification with the application. The verification includes the IND number, the date the subject protocol was submitted to FDA for the IND review, the IND serial number (if known), and a statement that the IND contains the same protocol as proposed in the grant application and that this

IND is active (not under review or on hold).

- (d) Protocols that would otherwise be eligible for an exemption from the IND regulations must be conducted under an IND to be eligible for funding under this FDA grant program.

- (e) If the sponsor of the IND is other than the principal investigator listed on the application, a letter from the sponsor permitting access to the IND must be submitted. Both the principal investigator named in the application and the study protocol must have been submitted to the IND.

- (f) Studies of already approved products are also subject to these IND requirements.

4. The requested budget must be within the limits as stated in this request for applications. Any application received that requests support over the maximum amount allowable for that particular study will be considered nonresponsive.

5. Proposed consent forms, assent forms, and any other information given to a subject, should be included in the grant application.

6. 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.

7. Applicants must follow guidelines named in the PHS 398 (Rev. 5/01) or (Rev. 4/98) grant application kit.

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 first review to determine whether the proposed study will provide data that could result in or 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.

##### C. Scientific/Technical Review Criteria

The ad hoc expert panel will provide the first review. The application will be judged 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 to include the rationale for the statistical procedures.

3. The statistical justification for the number of patients chosen for the study

(to demonstrate superiority of the gentamicin treatment arm to that of a no treatment historical control), 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.

The priority score will be based on the scientific/technical review criteria cited in section V.C of this document. Also, the reviewers may advise the program staff about the appropriateness of the proposal to the goals of the OPDDPI grant program described under Program Research Goals in section I of this document.

## VI. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 5/01) or (Rev. 4/98) or the original and two copies of the PHS 5161-1 (Rev. 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Rosemary Springer (see **ADDRESSES**). State and local governments may use the PHS 398 (Rev. 5/01) or (Rev. 4/98) application form instead of the PHS 5161-1. The application receipt date is July 29, 2002.

Other than evidence of final IRB approval, no material will be accepted after the receipt date. The mailing package and item two of the application face page should be labeled, "Response to RFA-FDA-CDER-02-2".

## VII. 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, unless they arrive too late for orderly processing. 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.) Do not send applications to the Center for Scientific Research (CSR), 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. Applicants should know FDA does not adhere to the page limits or the type size and line spacing requirements imposed by NIH on its applications. 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) or (Rev. 4/98). All "General Instructions" and "Specific Instructions" in the application kit should be followed except for the receipt dates and the mailing label address. Do not send applications to the CSR, NIH. Applications from State and local governments may be sent on Form PHS 5161-1 (Rev. 7/00) or Form PHS 398 (Rev. 5/01) or (Rev. 4/98). The face page of the application should reflect the request for applications number RFA-FDA-CDER-02-2. The title of the proposed study should include the name of the product (gentamicin versus either doxycycline or streptomycin) and the disease/disorder (human plague) to be studied and the IND number. The format for all following pages of the application should be single-spaced and single-sided. Data information included in the application will generally not be publicly available prior to the funding of the application. Data included in the application may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61) even after funding has been granted. To designate information that an applicant believes to be trade secret or confidential commercial information that remains exempt from disclosure after funding, sponsors should use the legend below. Information collection requirements requested on Form PHS 398 (Rev. 5/01) and (Rev. 4/98) has been sent by the PHS to the Office of Management and Budget (OMB) and was approved and assigned OMB control number 0925-0001.

### C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application which have been specifically identified by the applicant as containing restricted information shall not be disclosed to the public or used except for evaluation purposes.

Dated: May 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-13461 Filed 5-29-02; 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 June 13, 2002, from 8 a.m. to 5:30 p.m., and on June 14, 2000, from 8 a.m. to 1:30 p.m.

*Location:* Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact:* 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 June 13, 2002, the following committee updates are tentatively scheduled: (1) End user notification, and (2) human immunodeficiency virus (HIV) rapid tests. The committee will hear an informational presentation on the shortage of western blot tests for HIV and electronic submission of biological