(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

license applications (BLAs), and discuss and provide recommendations on standards for recovered plasma. In the afternoon, the committee will hear presentations, discuss, and make recommendations on the uniform donor history questionnaire. On June 14, 2002, the following committee updates are tentatively scheduled: (1) Summaries of FDA/Plasma Protein Therapeutic Association workshop on comparability of plasma derivatives, and (2) the American Association of Blood Bank conference on oxygen therapeutics. The committee will hear an informational presentation on premarket submissions: In-vitro diagnostic software and instruments. The committee will hear presentations, discuss, and make recommendations on the warning label for hetastarch and bleeding.

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 June 3, 2002. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m. and between approximately 4 p.m. and 4:30 p.m. on June 13, 2002; and between approximately 12 noon and 12:30 p.m. on June 14, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 3, 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 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.

FDA regrets that it was unable to publish this notice 15 days prior to the June 13 and 14, 2002, Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: May 23, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–13586 Filed 5–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food 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: Food 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 July 23 through July 25, 2002, from 8:30 a.m. until 4:30 p.m.

Location: Sheraton College Park Hotel, Salons A, B, and C, 4095 Powder Mill Rd., Beltsville, MD 20705, 301–937–4422.

Contact Person: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2397, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The purpose of the meeting is to discuss FDA's consumer advisory regarding methyl mercury and seafood.

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 July 11, 2002. Oral presentations from the public will be scheduled between approximately 4:30 p.m. and 5 p.m. on July 23, 2002, and between approximately 1:30 p.m. and 2 p.m. on July 24, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 11, 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 Catherine DeRoever 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: May 23, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–13584 Filed 5–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food 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: Food 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 20, 2002, from 9 a.m. to 6 p.m. and June 21, 2002, from 8:30 a.m. to 2 p.m.

Location: Holiday Inn, Ballrooms A and B, 10000 Baltimore Ave., College Park, MD 301–345–6700.

Contact Person: Constance J. Hardy, Center for Food Safety and Applied Nutrition (HFS–811), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–