## 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 years (FY) 2004 and 2005. This announcement supercedes the previous announcement of this program, which was published in the **Federal Register** of August 27, 2002 (67 FR 55020).

**DATES:** For FY 2004, the application receipt date is October 13, 2003. For FY 2005, the application receipt dates are April 7, 2004, and October 6, 2004.

**ADDRESSES:** Application requests and completed applications should be submitted to Maura Stephanos, Grants Management Officer, Grants and Assistance Agreements, Division of Contracts and Grants Management (HFA–531), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183, 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.[1] Applications may also be obtained from the OPD on the Internet at *http://www.fda.gov/orphan* or *http://grants.nih.gov/grants/funding/phs398/phs398.html*.[2]

**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, Director, Orphan Products Grants Program, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6A–55, Rockville, MD 20857, 301–827–3666, e-mail: *dlewis@oc.fda.gov*.

[1] Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH).

[2] FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

**SUPPLEMENTARY INFORMATION:** Except for applications for studies of medical foods that do not need premarket approval, FDA will only award grants to support premarket clinical studies to determine 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.

Applicants for Public Health Service (PHS) clinical research grants are encouraged to include minorities and women in study populations so research findings can be of benefit to all people at risk of the disease or condition under study. It is recommended that applicants place special emphasis on including 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.

The 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 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://www.healthypeople.gov/*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) Internet viewers should proceed to ''Publications.''

## I. Program Research Goals

The 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 to support 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 on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. Applicants must include in the application's ''Background and Significance'' section an explanation of how the 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. 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. Award Amount*

Of the estimated FY 2004 funding ($13.2 million), approximately $9.2 million will fund noncompeting continuation awards, and approximately $4 million will fund 10 to 12 new awards. The expected start date for the FY 2004 awards will be April 1, 2004. The estimated FY 2005 funding is anticipated to be the same as FY 2004. The expected start date for the FY 2005 awards will begin January 1, 2005.

All applications received for the October 13, 2003, due date that are

recommended for approval but not funded using FY 2004 funds will remain in competition for FY 2005 funds along with those applications received for the April 7, 2004, and October 6, 2004, due dates. Applications submitted for the first due date may be withdrawn and resubmitted for the second due date.

Grants will be awarded for $150,000 or $300,000 in direct costs a year, plus applicable indirect costs, for up to 3 years. Applications for the smaller grants ($150,000) may be for phase 1, 2, or 3 studies. Study proposals for the larger grants ($300,000) must be for studies continuing in phase 2 or phase 3 of investigation. Phase 1 studies include the initial introduction of an investigational new drug or device into humans, are usually conducted in healthy volunteer subjects, and are designed to determine the metabolic and pharmacological actions of the product in humans, the side effects including those associated with increasing drug doses and, if possible, to gain early evidence on effectiveness. Phase 2 studies include early controlled clinical studies conducted to evaluate the effectiveness of the product for a particular indication in patient's with the disease or condition and to determine the common short-term side effects and risks associated with it. Phase 3 studies 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 each year of requested support may not exceed the $150,000 or $300,000 direct cost limit, whichever is applicable.

*C. Eligibility*

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

*D. 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) compliance with regulatory requirements of the investigational new drug (IND)/investigational device exemption (IDE), and (3) availability of Federal funds.

*E. 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 or if the IND/IDE for the proposed study is not active and in regulatory compliance, no award will be made. Documentation of assurances with the Office of Human Research Protection (OHRP) (see section III.A of this document) should be on file with the FDA grants management office before an award is made. In order to avoid funding studies that may not receive or may experience a delay in receiving institutional review board (IRB) approval, documentation of IRB approval for all performance sites must be on file with the FDA grants management office before an award to fund the study will be made. In addition, if a grant is awarded, grantees will be informed of any additional documentation that should be submitted to FDA's IRB. This grant program does not require the applicant to match or share in the project costs if an award is made.

*F. Dun and Bradstreet Number (DUNS)*

Beginning October 1, 2003, applicants will be required to have a DUNS number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number call 1–866–705–5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

**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 OHRP (45 CFR part 46). Applicants are advised to visit the OHRP Internet site at *http://ohrp.osophs.dhhs.gov/* (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**) for guidance on human subjects issues. The requirement to file an assurance applies to 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 responsibility for protecting human subjects under the award. The awardee institution is also responsible for, among other things, 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 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.

The clinical protocol should comply with ICHE6 ''Good Clinical Practice Consolidated Guidance'' which states an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Applicants are encouraged to review the regulations, guidances and information sheets on Good Clinical Practice cited on the Internet at *http://www.fda.gov/oc/gcp/*.

*B. Key Personnel Human Subject Protection Education*

The awardee institution is responsible for ensuring that all key personnel receive appropriate training in their human subject protection responsibilities. Key personnel include all principal investigators, coinvestigators, and performance site investigators responsible for the design and conduct of the study. Neither DHHS, FDA, nor OPD prescribes or endorses 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/*[3] and by OHRP at *http://ohrp.osophs.dhhs.gov/educmat.htm*.[4] Also, the University of Rochester has made available its training program for individual investigators. Its manual can be obtained through Centerwatch, Inc., at *http://www.centerwatch.com*.[5] Within 30 days of the award, the principal investigator should provide a letter to the FDA grants management office 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 Officer.

*C. Informed Consent*

Consent forms, assent forms, and any other information given to a subject are part of the grant application and must be provided, even if in a draft form. 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. Review Procedures and Criteria

*A. Review Procedures*

FDA grants management and program staff will review all applications sent in response to this notice. To be responsive, an application must be submitted in accordance with sections II.B, II.C, IV.B, and V of this document, and must bear the original signatures of both the principal investigator and the applicant institution's/organization's authorized official. Applications found to be nonresponsive will be returned to the applicant without further consideration. 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 **FOR FURTHER INFORMATION CONTACT**).

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 or his designee.

*B. Program Review Criteria*

1. Applications must propose clinical trials 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 as follows:

- 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 principal investigator named 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 free 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. Any application received that requests support over the maximum amount allowable for that particular study will be considered nonresponsive.

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. The narrative portion of the application (excluding appendices) should be no more than 100 pp., single-spaced, printed on 1 side, with 1/2-inch margins, and in unreduced 12-point font. The application should not be bound.

*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 design of data and safety monitoring plans.

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 request for applications (RFA).

A score will be assigned based on the scientific/technical review criteria. The review panel may advise the program

[3,4,5] FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

staff about the appropriateness of the proposal to the goals of the OPD grant program described in section I of this document.

**V. 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 must 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. 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 must be labeled ''Response to RFA–FDA–OPD–2004–1'' or ''RFA–FDA–OPD–2005–1,'' whichever is applicable. 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.

Also, if an application is submitted for the October 13, 2003, due date and is not funded, and an application for the same study is then resubmitted for either the April 7, 2004, or October 6, 2004, due dates for FY 2005 funding, the original, unfunded application will be administratively withdrawn. Resubmissions are treated as new applications; therefore, the applicant for a resubmitted application must 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 resubmitted application. Applicants must follow guidelines named in the PHS 398 (Rev. 5/01) grant application instructions.

**VI. Method of Application**

*A. Submission Instructions*

Applications will be accepted from 8 a.m. to 4:30 p.m., Monday through Friday until the established receipt dates. Applications will be considered received on time if hand delivered to the address noted previously before the established receipt dates or sent or mailed by the receipt date as shown by a legible U.S. Postal Service dated postmark or a legible dated 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 forwarded to FDA and received after the applicable due date will be judged nonresponsive and returned to the applicant. Applications must be submitted via U.S. mail or commercial carrier or hand delivered as stated previously. Currently, 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 or on the OPD Web site (see **ADDRESSES**) must be followed except for the receipt dates and the mailing label address. The face page of the application must reflect the request for applications number RFA-FDA-OPD–2004–1 or RFA-FDA-OPD–2005–1, whichever is applicable. The title of the proposed study must include the name of the product and the disease/disorder to be studied and the IND/IDE number. The remaining portion of the application may not exceed 100 pp. in length and must be single-spaced, printed on 1 side, in 12-point font, and unbound.

Applicants have the option of omitting from the application copies (but not from 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.

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

Data and information included in the application will generally not be publicly available prior to the funding of the application. After funding has been granted, data and information included in the application 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).

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.

**VII. Reporting Requirements and Monitoring Activities**

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. For continuing grants, an annual program progress report is also required. For such grants, 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-mails between the project officer/grants management officer and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the grant, including those 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.

**VIII. Clinical Trials Data Bank**

The Food and Drug Modernization Act of 1997 requires studies of drugs for serious or life-threatening diseases conducted under FDA's IND regulations to be entered into the Clinical Trials Data Bank (CTDB).

This databank provides patients, family members, healthcare providers, researchers, and members of the public easy access to information on clinical trials for a wide range of diseases and conditions. The U.S. National Library of Medicine has developed this site in collaboration with NIH and FDA. The databank is available to the public through the Internet at *http://clinicaltrials.gov*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The CTDB contains: (1) Information about clinical trials, both federally and privately funded, of experimental treatments for patients with serious or life-threatening diseases; (2) a description of the purpose of each experimental drug; (3) patient eligibility criteria; (4) the location of clinical trial sites; and (5) point of contact for those wanting to enroll in the trial.

All applications that are funded through the OPD grant program are required to enter into the CTDB information about the study being funded. The OPD program staff will provide more information to grantees about entering the required information in the CTDB after awards are made.

Dated: July 30, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–20198 Filed 8–7–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting.

*Name:* Advisory Committee on Interdisciplinary, Community-Based Linkages.

*Dates and Times:*
September 7, 2003, 5 p.m.–8 p.m.
September 8, 2003, 8:30 a.m.–5:30 p.m.
September 9, 2003, 8:30 a.m.–4 p.m.

*Place:* The Washington Terrace Hotel, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

*Status:* The meeting will be open to the public.

*Agenda:* Agenda items will include, but not be limited to: Welcome; plenary session on cultural competency and diversity for the grant programs under the purview of the Committee with presentations by speakers representing the Department of Health and Human Services (DHHS), constituent groups, field experts and committee members. Meeting content will focus on how cultural competency and diversity relate to health status outcomes. The following topics could be addressed at the meeting: Does cultural competency impact on health status outcomes; How do Titles VII and VIII programs address cultural competency; and What measures of health outcomes are critical to linking effectiveness of cultural competency to Titles VII and VIII programs.

Proposed agenda items are subject to change as priorities dictate.

*Public Comments:* Public comment will be permitted before lunch and at the end of the Committee meeting on September 8, 2003. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, with a copy of their presentation to: Jennifer Donovan, Deputy Executive Secretary, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 9–105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–8044.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The Division of State, Community and Public Health will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file a request in advance for a presentation, but wish to make an oral statement may register to do so at the Washington Terrace Hotel, Washington, DC, on September 8, 2003. These persons will be allocated time as the Committee meeting agenda permits.

*For Further Information Contact:* Anyone requiring information regarding the Committee should contact Jennifer Donovan, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 9–105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–8044.

Dated: August 1, 2003.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 03–20249 Filed 8–7–03; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel, National Research Service Award.

*Date:* September 21–23, 2003.

*Time:* 2 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Judy S. Hannah, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892, 301/435–0287.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health; HHS)

Dated: August 4, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–20297 Filed 8–7–03; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Biomedical Imaging and Bioengineering; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of meetings of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.