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Dated: December 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24223 Filed 12–15–05; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing changes to its Office of Orphan Products Development (OPD) grant program for fiscal year (FY) 2007 and FY 2008. This announcement supersedes the previous announcement of this program, which was published in the **Federal Register** of January 14, 2005 (70 FR 2642). Please note that there is only one receipt date for FY 2007 and one receipt date for FY 2008.

1. Background

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 per year.

2. Program Research Goals

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, documentation to support the estimated prevalence of the orphan disease or condition and 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 Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) and regulations issued under it.

II. Award 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 safety and effectiveness for approval under section 505 or 515 of the act (21 U.S.C. 355, or 360e) or safety, purity, and potency for licensing 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 (42 U.S.C. 241). 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.

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

1. 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 National Institutes of Health (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, section 351 of the PHS Act, and regulations issued under any of these sections.

2. Award Amount

Of the estimated FY 2007 funding ($14.2 million), approximately $10 million will fund noncompeting continuation awards, and approximately $4.2 million will fund 10 to 12 new awards subject to availability of funds. It is anticipated that funding for the number of noncompeting continuation awards and new awards in FY 2008 will

be similar to FY 2007. The earliest expected start date for the FY 2007 and FY 2008 awards will be November 1, 2006, and November 1, 2007, respectively. Grants will be awarded up to $200,000 or up to $350,000 in total (direct plus indirect) costs per year for up to 3 years. Please note that the dollar limitation will be total costs, not direct costs as in previous years.

Applications for the smaller grants ($200,000) may be for phase 1, 2, or 3 studies. Study proposals for the larger grants ($350,000) must be for studies continuing in phase 2 or 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 patients 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 $200,000 or $350,000 total cost limit, whichever is applicable.

3. 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 the following factors: (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.

4. Funding Plan

In addition to the requirement for an active IND/IDE discussed in section V.1.B.(4) of this document, documentation of assurances with the Office of Human Research Protection (OHRP) (see section IV.5.A of this document) must be on file with FDA's Grants Management Office before an award is made. Any institution receiving Federal funds must have an institutional review board (IRB) of record even if that institution is overseeing research conducted at other performance sites. To avoid funding studies that may not receive, or may experience a delay in receiving, IRB approval, documentation of IRB approval and Federal Wide Assurance (FWA or assurance) for the IRB of record and all performance sites must be on file with FDA's 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.

5. Dun and Bradstreet Number (DUNS)

As of October 1, 2003, applicants are now 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 that uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call Dun and Bradstreet at 1–866–705–5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

6. Central Contractor Registration

In anticipation of the grants.gov electronic application process, applicants are encouraged to register with the Central Contractor Registration (CCR) database. This database is a governmentwide repository of commercial and financial information for all organizations conducting business with the Federal Government. Registration with CCR will eventually become a requirement for grant applicants and is consistent with the governmentwide Management Reform to create a citizen-centered web presence and build e-gov infrastructures in and across agencies to establish a ''single face to industry.'' The preferred method for completing registration is on the Internet at *http://www.ccr.gov* (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site or its address after this document publishes in the **Federal Register**). This Web site provides a CCR handbook with detailed information on data applicants will need prior to beginning the online registration, as well as steps to walk applicants through the registration process. Applicants must have a DUNS number to begin registration and should call Dun and Bradstreet, Inc., at the number listed in the previous paragraph if they do not have one.

In order to access grants.gov, applicants will be required to register with the Credential Provider. Information about this is available at *http://www.grants.gov/CredentialProvider* (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site or its address after this document publishes in the **Federal Register**).

7. Clinical Trials Data Bank (CTDB)

The Food and Drug Modernization Act of 1997 requires that certain information be entered into CTDB for federally and privately funded clinical trials conducted under an IND if a drug is being used to treat a serious or life-threatening disease or condition and if the trial is to test effectiveness (42 U.S.C. 282(j)(3)(A)). Information on noneffectiveness trials for drugs to treat conditions not considered serious or life-threatening may also be entered into this database, but such information is not required.

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 and its address, but we are not responsible for subsequent changes to the Web site or its address after this document publishes in the **Federal Register**).

CTDB contains the following information: (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) the patient eligibility criteria; (4) the location of clinical trial sites; and (5) the point of contact for those wanting to enroll in the trial. OPD program staff will provide more information to grantees about entering the required information in CTDB after awards are made.

III. Eligibility Information

1. Eligible Applicants

The grants are available to any foreign or domestic, public or private, for-profit or nonprofit entity (including State and local units of government). Federal

agencies that are not part of the Department of Health and Human Services (HHS) may apply. Agencies that are part of HHS may not apply. 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. An application that has received two prior disapprovals is not eligible to apply.

2. Cost Sharing or Matching

Cost sharing is not required.

IV. Application and Submission

1. Addresses to Request Application

If submitted as a paper copy, application requests and completed applications should be submitted to Cynthia Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cynthia.polit@fda.hhs.gov* or *cpolit@oc.fda.gov*. Applications that are hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2105, Rockville, MD 20852. Applications may also be obtained from OPD on the Internet at *http://www.fda.gov/orphan*. Do not send applications to the Center for Scientific Research (CSR), NIH.

2. Content and Form of Application

A. General Information

FDA is accepting new applications for this program electronically via *www.grants.gov*. Applicants are encouraged to apply electronically by visiting the Web site *www.grants.gov* and following instructions under ''Apply for Grants.'' The required application, SF 424RR (Research and Related Portable Document Formats) can be completed and submitted online. The package should be labeled ''Response to RFA–FDA–OPD–2007'' or ''Response to RFA–FDA–OPD–2008''. If you experience technical difficulties with your online submission you should contact either the grants.gov Customer Response Center or Cynthia Polit (see Addresses to Request Application in section IV.1 of this document).

To comply with the President's Management Agenda, HHS is participating as a partner in the new governmentwide grants.gov Web site. Users of grants.gov will be able to download a copy of the application package, complete it offline, and then upload and submit the application via the grants.gov Web site. We encourage your participation in the grants.gov project. When you enter the grants.gov Web site, you will find information about submitting an application electronically through the Web site.

In order to apply electronically, the applicant must have a DUNS number and register in the CCR database as described in sections II.5 and II.6 of this document.

If submitted other than electronically, please call Cynthia Polit for guidance (see Addresses to Request application in section IV.1 of this document) prior to submission. For hard copies, an original and two copies of the completed Grant Application Form PHS 398 (Rev. 5/01) with three copies of the appendices must be submitted to Cynthia Polit (see Addresses to Request Application in section IV.1 of this document). Other than evidence of final IRB approval, FWA or assurance, and certification of adequate supply of study product, no material will be accepted for inclusion in the grant application after the receipt date.

In unusual circumstances, additional information may be considered, on a case by case basis, for inclusion in the ad hoc expert panel review. However, FDA cannot assure inclusion of any information after the receipt date other than evidence of final IRB approval, FWA or assurance, and certification of adequate supply of study product.

The mailing package and the application face page must be labeled ''Response to RFA–FDA–OPD–2007'' for FY 2007 and ''Response to RFA–FDA–OPD–2008'' for FY 2008. If an application for the same study was submitted in response to a previous request for application (RFA) but has not yet been funded, an application in response to this notice will be considered a request to withdraw the previous application. The applicant for a resubmitted application should 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.

An application that has received two prior disapprovals is not eligible for resubmission.

B. Format for Application

For FY 2007, if submitted electronically, the application must be on SF424 Research and Related Portable Document Format. If submitted in paper copy, the application must be submitted on Grant Application Form PHS 398 (Rev. 5/01). All ''General Instructions'' and ''Specific Instructions'' in the application kit or on OPD's Web site (see Addresses to Request Application in section IV.1 of this document) must be followed except for the receipt dates and the mailing label address in the PHS 398 package. The face page of the application, either electronic or paper, should reflect RFA number RFA–FDA–OPD–2007. 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 narrative portion of the application may not exceed 100 pages in length and must be single-spaced, printed on 1 side, in 12-point font, and unbound. The appendices should also not exceed 100 pages in length (separate from the narrative portion of the application).

For FY 2008, all applications must be submitted electronically through grants.gov. Exceptions may be made in unusual circumstances and on a case-by-case basis. If electronic submission is impossible, please contact the Grants Management Office (see Addresses to Request Application in section IV.1 of this document). The face page of the application should reflect RFA number RFA–FDA–OPD–2008. 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 narrative portion of the application may not exceed 100 pages in length and must be single-spaced, printed on 1 side, in 12-point font. The appendices should also not exceed 100 pages in length (separate from the narrative portion of the application).

For all applications in FY 2007 and FY 2008, 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 review division staff.

Data and information included in the application generally will 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 21 CFR 20.61, 20.105, and 20.106). By accepting funding, the applicant agrees to allow OPD to publish specific information about the grant.

Information collection requirements requested on Form PHS 398 (Rev. 5/01) have been sent by 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 SF424 Research and Related Portable Document Formats were approved and assigned OMB control number 4040–0001.

3. Submission Dates and Times

For FY 2007, the application receipt date is March 14, 2006, and for FY 2008, the application receipt date is February 7, 2007. Please note that there is only one receipt date for FY 2007 and one receipt date for FY 2008. Applications submitted electronically must be received by the close of business on the established receipt date.

The protocol in the grant application should be submitted to IND/IDE no later than February 13, 2006, for FY 2007 and no later than January 8, 2007, for FY 2008.

For FY 2007, if submitted as a paper copy, applications will be accepted from 8 a.m. to 4:30 p.m., Monday through Friday, until the established receipt date. Applications will be considered received on time if hand-carried to the address noted previously (see Addresses to Request Application in section IV.1 of this document) before the established receipt date, 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 (applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office). Private metered postmarks shall not be acceptable as proof of timely mailing. If submitted electronically, applications must be received by close of business on the published receipt date.

Applications not received on time will not be considered for review and will be returned to the applicant. Please do not send applications to CSR at NIH. Any application sent to NIH/CSR that is forwarded to FDA's Grants Management Office and not received in time for orderly processing will be judged nonresponsive and returned to the applicant. Applications must be submitted via U.S. mail or commercial carrier or hand-carried as stated previously, unless submitted electronically.

4. Intergovernmental Review

This program is not subject to review under the terms of Executive Order 12372.

5. Funding Restrictions

A. Protection of Human Research Subjects

All institutions engaged in human subject research financially supported by HHS must file an assurance of protection for human subjects with OHRP (45 CFR part 46). Applicants are advised to visit OHRP's Web site at *http://www.hhs.gov/ohrp* for guidance on human subjects issues (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site or its address after this document publishes in the **Federal Register**).

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 HHS 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. An awardee institution must, therefore, have its own IRB of record and assurance. The IRB of record may be an IRB already being used by one of the ''performance sites,'' but it must specifically be registered as the IRB of record with OHRP.

For further information, 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'' in the PHS 398 package or as posted on the grants.gov application Web site.

The clinical protocol should comply with ICHE6 ''Good Clinical Practice Consolidated Guidance'' which sets 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. HHS, FDA, and OPD do not 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-ed.od.nih.gov/CBTs/Assurance/login.asp* (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the Web sites or their addresses after this document publishes in the **Federal Register**).

Within 30 days of the award, the principal investigator should provide a letter to FDA's Grants Management Office that 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 cosigned by an institution official and sent to FDA's Grants Management Office.

6. Other Submission Requirements

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 HHS regulations at 45 CFR 46.116 and 21 CFR 50.25 for details regarding the required elements of informed consent.

V. Application Review Information

1. Criteria

A. General Information

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 the

requirements of this notice and must bear the original signatures of both the principal investigator and the applicant institution's/organization's authorized official if submitted as a paper copy in FY 2007. The original signature requirement does not apply to applications submitted electronically.

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 applications. Please direct all questions of a technical or scientific nature to OPD program staff and all questions of an administrative or financial nature to the grants management staff (see Agency Contacts in section VII of this document).

B. Program Review Criteria

(1) Applications must propose clinical trials intended to provide safety and/or efficacy data.

(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 ''Background and Significance'' section of the application must contain information documenting that the prevalence, not incidence, of the population to be served by the product is fewer than 200,000 individuals in the United States. The applicant should include 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 FDA's IND/IDE review 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 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 in both the IND/IDE and in the grant application. The principal investigator(s) named in the application and in the study protocol must be 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 and medical devices that are classified as nonsignificant risk (NSR) are exempt from these IND/IDE requirements. Applicants studying an NSR device should provide a letter in the application from FDA's Center for Devices and Radiologic Health indicating the device is an NSR device.

(5) The requested budget must be within the limits, either $200,000 in total costs per year for up to 3 years for any phase study, or $350,000 in total costs per 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. If negotiations with a sponsor to supply the study product are underway but have not been finalized at the time of application, please provide a letter indicating such in the application. Verification of an adequate supply of the study product will be necessary before an award is made.

(7) The protocol should be submitted in the application. The narrative portion of the application should be no more than 100 pages, single-spaced, printed on 1 side, with 1/2-inch margins, and in unreduced 12-point font. The appendices should also be no more than 100 pages (separate from the narrative portion of the application). 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 the 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 and monitoring; and

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

2. Review and Selection Process

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.

A score will be assigned based on the scientific/technical review criteria. The review panel may advise the program staff about the appropriateness of the proposal to the goals of OPD's grant program.

3. Anticipated Announcement and Award

Notification regarding the results of the review is anticipated by September 30, 2006, for FY 2007 and by September 30, 2007, for FY 2008. The earliest expected start date for the FY 2007 awards will be November 1, 2006, and for FY 2008 awards, the earliest expected start date will be November 1, 2007.

VI. Award Administration Information

1. Award Notices

If receiving an award, applicants will be notified by FDA's Grants Management Office. Awards will either be issued on a Notice of Grant Award (PHS 5152) signed by FDA's Chief Grants Management Officer and be sent

to successful applicants by mail or will be transmitted electronically.

2. Administrative Requirements

Applicants must adhere to the requirements of this notice. Special terms and conditions regarding FDA regulatory requirements and adequate progress of the study may be part of the award notice.

3. Reporting

A. 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. 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 the status of their IND/IDE ''active'' and ''in effect,'' that is, not on ''clinical hold.'' Failure to meet regulatory requirements will be grounds for suspension or termination of the grant.

B. Monitoring Activities

The program project officer will monitor grantees periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project officer/grants management officer and the principal investigator. Information including but not limited to study progress, enrollment, problems, adverse events, changes in protocol, and study monitoring activities will be requested. Periodic site visits with officials of the grantee organization also may 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.

VII. Agency Contacts

For issues regarding the administrative and financial management aspects of this notice: Cynthia Polit (see Addresses to Request Application in section IV.1 of this document).

For issues regarding the programmatic aspects 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: *debra.lewis@fda.gov* or *dlewis@oc.fda.gov*.

VIII. Other Information

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).

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of HHS, by a court, or required by another Federal law, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: December 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24164 Filed 12–16–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Sentinel Centers Network (SCN) Core Data Set (OMB No. 0915–0268)—Extension

HRSA's Bureau of Primary Health Care (BPHC) established the Sentinel Centers Network (SCN) to assist in addressing critical quality, programmatic, and policy issues. Health centers identified as having adequate infrastructure and commitment through the competitive contract process have generated data for quality and program analyses and for projects on topics that have immediate programmatic impact. Health centers submit core data periodically extracted from existing information systems. These core data comprise patient, encounter, and practitioner level information including patient demographics, insurance status, clinical diagnoses and procedures, outcomes, and practitioner characteristics. Since all data obtained from the participant health centers are extracted/compiled from existing information systems and not through primary data collection, burden is minimized. In addition, each participant site receives technical assistance as needed to reduce burden and facilitate data submission.

The annual burden estimate for this activity is as follows:

Type of respondent	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Sites	43	2	86	8	688