Appropriation will unquestionably affect what we will be able to commit to accomplish in FY 2008. Accordingly, FDA requests comments on broad program areas that should continue to be a priority as well as new program areas or activities that should be added as a high priority for FY 2008.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–12884 Filed 7–2–07; 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: RFA–FD08–001; Research Project Grants (R01); Catalog of Federal Domestic Assistance Number: 93.103

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 years (FY) 2009 and 2010. This announcement supersedes the previous announcement of this program, which was published in the **Federal Register** of December 19, 2005 (70 FR 75198).

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 a year. Additional information about OPD is available on FDA's Web site at *www.fda.gov/orphan*.

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. 331 *et seq.*), regulations issued under it, and applicable Department of Health and Human Services (HHS) statutes and regulations.

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 (CFDA), No. 93.103.

1. Award Instrument

Support will be in the form of a research project (R01) grant. All awards will be subject to all policies and requirements that govern the research grant programs of the PHS Act as incorporated in the HHS Grants Policy Statement, dated October 1, 2006, (*http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*), 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 (21 U.S.C. 360b), section 351 of the PHS Act, regulations issued under any of these sections, and other applicable HHS statutes and regulations regarding human subject protection.

2. Award Amount

Of the estimated FY 2009 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 2010 will be similar to FY 2009. Grants will be awarded up to $200,000 or up to $400,000 in total (direct plus indirect) costs per year for up to 4 years. Please note that the dollar limitation will apply to total costs, not direct costs, as in previous years. A fourth year of funding is available only for phase 2 or 3 clinical studies. Applications for the smaller grants ($200,000) may be for phase 1, 2, or 3 studies. Study proposals for the larger grants ($400,000) must be for studies continuing in phase 2 or 3 of investigation.

Phase 1 studies include the initial introduction of an investigational new drug (IND) 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. In some Phase 1 studies that include subjects with the rare disorder, it may also be possible to gain early evidence on effectiveness.

Phase 2 studies include early controlled clinical studies conducted to: (1) Evaluate the effectiveness of the product for a particular indication in patients with the disease or condition and (2) 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 $400,000 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, third, or fourth year of noncompetitive continuation of support will depend on the following factors: (1) Performance during the preceding year; (2) compliance with regulatory requirements of IND/investigational device exemption (IDE); and (3) availability of Federal funds. A fourth year of funding is available only for phase 2 or 3 clinical studies.

4. Funding Plan

In addition to the requirement for an active IND/IDE discussed in section V.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 the FDA 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 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.

5. Dun and Bradstreet Number (DUNS)

Beginning October 1, 2003, applicants are 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 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

For the grants.gov electronic application process, applicants are required to register with the Central Contractor Registration (CCR) database. This database is a governmentwide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. Registration with CCR is a requirement and is consistent with the governmentwide management reform to create a citizen-centered Web presence and build electronic government (e-gov) infrastructures in and across agencies to establish a ''single face to industry.'' The preferred method for completing a registration is through the Internet at *http://www.ccr.gov*.[1] This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online registration, as well as steps to walk you through the registration process. You must have a DUNS number to begin your registration. Call Dunn & Bradstreet, Inc. at the telephone number listed in section II.5 of this document if you do not have a DUNS number.

In order to access grants.gov, an applicant will be required to register with the Credential Provider. Information about this process is available at *http://www.grants.gov/applicants/iregister_credential_provider.jsp*.

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 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

This grant program does not require the applicant to match or share in the project costs if an award is made.

IV. Application and Submission Information

1. Content and Form of Application Submission

A. General Information

FDA is accepting new applications for this program electronically via *www.grants.gov*. Applicants should apply electronically by visiting the Web site *www.grants.gov* and following instructions under ''Apply for Grants.'' The required application, SF424 R&R (Research & Related Portable Document Formats) can be completed and submitted online. We strongly encourage using the ''Tips'' posted on *www.grants.gov* under the announcement number when preparing your submission. If you experience technical difficulties with your online submission, you should contact either the grants.gov Customer Response Center *http://www.grants.gov/contactus/contactus.jsp* or Dianna Jessee, Grants Management Specialist (see **AGENCY CONTACTS** in section VII of this document).

To comply with the President's Management Agenda, HHS is participating as a partner in the new governmentwide grants.gov application 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. When you enter the grants.gov Web site, you will find information about submitting an application electronically through the Web site. In addition, this process is similar to the R01 Grant Application process currently used at NIH. You can visit the following Web site for helpful background on preparing to apply, preparing an application, and submitting an application to grants.gov: *http://era.nih.gov/ElectronicReceipt/*. 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.

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.

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

In FY 2009 and 2010, all applications must be submitted electronically through grants.gov. The application must be on SF424 R&R (Research and Related Portable Document Format). The title of the proposed study must include the name of the product and the

[1] (FDA has verified the non-FDA Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

disease/disorder to be studied and the IND/IDE number. The narrative portion, excluding appendices, of the application may not exceed 100 pages in length and must be single-spaced in 12-point font. The appendices should also not exceed 100 pages in length (separate from the narrative portion of the application).

2. Submission Dates and Times

For FY 2009, the application receipt date is February 6, 2008, and for FY 2010, the application receipt date is February 4, 2009. Please note that there is only one receipt date for FY 2009 and one receipt date for FY 2010. Applications must be received by the close of business on the established receipt date. Late applications may be accepted under extreme circumstances beyond the control of the applicant. Applications not received on time will not be considered for review and will generally be returned to the applicant.

The protocol in the grant application should be submitted to the IND/IDE no later than January 7, 2008, for FY 2009 and no later than January 5, 2009, for FY 2010.

3. Intergovernmental Review

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

4. 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 the OHRP (45 CFR part 46). Applicants are advised to visit the OHRP Web site at *http://www.hhs.gov/ohrp* for guidance on human subject protection 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 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 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. All human subject research regulated by FDA is also subject to FDA's regulations regarding the protection of human subjects (21 CFR parts 50 and 56). Applicants are encouraged to review the regulations, guidance, and information sheets on human subject protection and good clinical practice available on the Internet at *http://www.fda.gov/oc/gcp/*.

B. Key Personnel and 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, co-investigators, 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 *use http://www.hhs.gov/ohrp/education/*.

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 for each key 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 Specialist whose name appears on the official Notice of Grant Award (NGA).

5. 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. 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 **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 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 the applicable FDA 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 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 in both the IND/IDE and in the grant application. The name(s) of 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 free from these IND/IDE requirements. Applicants studying an NSR device should provide a letter in the application from FDA's Center for Devices and Radiological 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 $400,000 in total costs per year for up to 4 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 non-responsive.

6. In an appendix to the application, there must be evidence that the product to be studied is available to the applicant in the form and quantity needed for the clinical trial proposed. A current letter from the supplier as an appendix will be acceptable. If negotiations regarding the supply of 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 adequate supply of 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, 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).

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 the National Cancer Institute, National Cancer Advisory Board (NCAB) 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 the OPD grant program.

VI. Award Administration Information

1. Award Notices

A formal notification in the form of an NGA will be provided to the applicant organization. The NGA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NGA will be generated via e-mail or hard copy from FDA to the authorized grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk. These costs may be reimbursed only to the extent they are considered allowable pre-award costs.

2. Administrative Requirements

All FDA grant awardees must adhere to the requirements stated in the RFA, the NGA, associated Terms and Conditions, as well as any relevant FDA or HHS statutory or regulatory requirements.

3. Reporting

A. Reporting Requirements

When multiple years are involved, awardees will be required to submit the Non-Competing Grant Progress Report (PHS 2590) annually and financial statements as required in the HHS Grants Policy Statement, dated October 1, 2006, (*http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*). 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 or specialist and the principal investigator. Information including, but not limited to, information regarding 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 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 the following: (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 applicable FDA and HHS regulatory requirements for the trial.

The grantee must file a final program progress report, financial status report, 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

FDA encourages your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas:

Scientific/Research Contact: 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.hhs.gov.*

Administrative/Financial Management Contact: Dianna L. Jessee, Grants Management Specialist, Division of Acquisition Support and Grants, Office of Acquisitions & Grant Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2141, Rockville, MD 20857, 301–827–7177, e-mail: *dianna.jessee@fda.hhs.gov*.

VIII. Other Information

Required Federal Citations

Clinical Trials Data Bank

The Food and Drug Administration Modernization Act of 1997 established a requirement that certain information be entered into the Clinical Trials Data Bank (CTDB) for federally and privately funded clinical effectiveness trials conducted under an IND for drugs (including trials for biological products) to treat serious or life-threatening diseases or conditions (42 U.S.C. 282(j)). Information on noneffectiveness trials, or for drugs to treat diseases or conditions not considered serious or life-threatening, may also be entered into this database but such information is not required. This CTDB 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 CTDB is available to the public through the Internet at *http://clinicaltrials.gov*.

The CTDB contains the following information: (1) Information about clinical trials, both federally and privately funded, of experimental treatments (drug and biological products) for patients with serious or life-threatening diseases or conditions; (2) a description of the purpose of each experimental drug; (3) the patient eligibility criteria; (4) a description of the location of clinical trial sites; and (5) a point of contact for those wanting to enroll in the trial. In 2007, the Best Pharmaceuticals for Children Act also required that the CTDB include a description of whether, and through what procedure, the manufacturer or sponsor of an IND will respond to a request for protocol exception, with appropriate safeguards, for single-patient and expanded access use of the investigational drug, particularly in children. The OPD program staff will provide more information to grantees about entering the required information in the CTDB after awards are made.

Freedom of Information Act (FOIA)

Data included in the application may be considered trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552) and FDA's statute and implementing regulations. FDA will protect trade secret or confidential commercial information to the extent allowed under applicable law.

Use of Animals in Research

Recipients of PHS support for activities involving live vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (*http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf*) as mandated by the Health Research Extension Act of 1985 (*http://grants.nih.gov/grants/olaw/references/hrea1985.htm*), and the USDA Animal Welfare Regulations (*http://www.nal.usda.gov/awic/legislat/usdaleg1.htm*) as applicable.

Inclusion of Women And Minorities in Clinical Research

Applicants for 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.

Inclusion of Children as Participants in Clinical Research

FDA regulations at 21 CFR part 50, subpart D contain additional requirements that must be met by IRBs reviewing clinical investigations regulated by FDA and involving children as subjects. FDA is part of HHS; accordingly, the research project grants under this program are supported by HHS, and HHS regulations at 45 CFR part 46, subpart D also apply to research involving children as subjects.

Standards for Privacy of Individually Identifiable Health Information

HHS issued final modification to the ''Standards for Privacy of Individually Identifiable Health Information,'' the ''Privacy Rule,'' on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR Web site *http://www.hhs.gov/ocr/* provides information on the Privacy Rule, including a complete regulation text and a set of decision tools on ''Am I a covered entity?'' Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD–03–025.html*.

Healthy People 2010

PHS is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a PHS-led national activity for setting priority areas. This Funding Opportunity Announcement is related to one or more of the priority areas. Potential applicants may obtain a

copy of ''Healthy People 2010'' at *http://www.health.gov/healthypeople*.

Smoke-Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Authority and Regulations

This program is described in the CFDA at *http://www.cfda.gov/* and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of sections 301 and 405 of the PHS Act as amended (42 U.S.C. 241 and 284) and under federal regulations 42 CFR part 52 and 45 CFR parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement, dated October 1, 2006, (*http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*).

Dated: June 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–12881 Filed 7–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0207]

Medical Devices; Cardiovascular Devices; Denial of Request for Change in Classification of Impedance Plethysmograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by Life Measurements Inc., to reclassify the SONAMET Body Composition Analyzers (BOD POD and PEA POD) from class II to class I. The agency is denying the petition because Life Measurements Inc., failed to provide sufficient new information to establish that general controls would provide reasonable assurance of the safety and effectiveness of the devices. This notice also summarizes the basis for the agency's decision.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4021.

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices Under the 1976 Amendments

The Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices under the 1976 amendments were class I (general controls), class II (performance standards), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device type; and (3) published a final regulation classifying the device type. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless: (1) The device type is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807, subpart E, of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a Premarket Application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section of the act provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in sections 513(e) and 515(b)(2)(A)(iv) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' upon which reclassification under section 513(e) of the act is based must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and § 560.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).) In addition, § 860.123(a)(6) (21 CFR 860.123(a)(6)) provides that a reclassification petition must include a ''full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present