clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 26, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Third-Party Review Under FDAMA (OMB Control No. 0910–0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) established a new section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. As with the third-party pilot program conducted previously by FDA, participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviews should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time. This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low to moderate risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

In the **Federal Register** of May 29, 2001 (66 FR 29142), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for accreditation	40	1	40	24	960
510k reviews conducted by accredited third parties	35	4	140	40	5,600
Total					6,560

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510(k) reviews	35	4	1,140	10	1,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burdens are explained as follows:

1. Reporting

a. *Requests for accreditation.* Under the agency's third-party review pilot program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. Under this expanded program, the agency anticipates that it will not see a significant increase in the number of applicants. Therefore, the agency is estimating that it will receive 40 applications. The agency anticipates that it will accredit 35 of the applicants to conduct third-party reviews.

b. *510(k) reviews conducted by accredited third parties.* In the 18 months under the third-party review pilot program, FDA received only 22 510(k)s that requested and were eligible for review by third parties. Because the third-party review program is not as limited in time, and is expanded in scope, the agency anticipates that the number of 510(k)s submitted for third-party review will remain the same as they were during the last OMB approval in 1998. The agency anticipates that it will receive approximately 140 third-party review submissions annually, i.e., approximately 4 annual reviews per each of the estimated 35 accredited reviewers.

2. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 140 annual submissions of 510(k)s for third-party review.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) is derived from agency records and experience.

Dated: August 20, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21529 Filed 8–24–01; 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.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes to its Orphan Products Development (OPD) grant program for fiscal year (FY) 2002. This announcement supersedes the previous announcement of this program, which was published in the **Federal Register** of August 8, 2000.

DATES: The application receipt dates are October 17, 2001, and March 5, 2002.

ADDRESSES: Application forms are available from, and completed applications should be sent to: Maura Stephanos, Grants Management Specialist, Division of Contracts and Procurement Management (HFA–522), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183, mstepha1@oc.fda.gov. Applications may also be obtained at OPD on the Internet at http://www.fda.gov/orphan. (Note: completed applications that are hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857.)

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management issues of this notice: Maura Stephanos (address and telephone number cited above).

Regarding the programmatic issues of this notice: Debra Y. Lewis, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 15A–08, Rockville, MD 20857, 301–827–3666, dlewis@oc.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the expected availability of FY 2002 funds for awarding grants to support clinical trials on the safety and effectiveness of products for a rare disease or condition (that is, one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Depending on FY 2002 funding, $12.5 million should be available, of which approximately $8.5 million will be for noncompeting continuation awards. This will leave $4 million for funding 12 to 15 new applications. The first part of the funding cycle will award about $1 million to successful applications received on the October 17, 2001 due date. These awards would start after March 1, 2002. All approved applications not funded in the first part of the funding cycle will remain in competition for the second part of the funding cycle. The expected start date for these applications will be September 30, 2002. Applications submitted for the first due date may be withdrawn and resubmitted for the second due date.

Any phase clinical trial is eligible for up to $150,000 in direct costs a year, plus applicable indirect costs, for up to 3 years. Phase 2 and 3 clinical trials are eligible for up to $300,000 in direct costs a year, plus applicable indirect costs, for up to 3 years.

FDA will support the clinical studies covered by this notice under the authority of section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103. The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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

PHS policy is that applicants for PHS clinical research grants should include minorities and women in study populations so research findings can be of benefit to all people at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy applies to research subjects of all ages. If women or minorities are excluded or poorly represented in clinical research, the applicant should provide a clear and compelling rationale that shows inclusion is inappropriate.

I. Program Research Goals

OPD was created to identify and promote the development of orphan products. The OPD grant program defines orphan products as 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 a year.

One way to make orphan products available is to support clinical research to find out whether the products are safe and effective. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued under it.

The goal of FDA's OPD grant program is 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 that will either result in or substantially contribute to approval of these products. Applicants should keep this goal in mind and must include an explanation in the application's ''Background and Significance'' section of how their proposed study will either help gain product approval or provide essential data needed for product development. The applicant should provide a summary of any meetings or discussions about the clinical study that have occurred with FDA reviewing division staff as an appendix to the application.

Except for medical foods that do not need premarket approval, FDA will only consider awarding grants to support premarket clinical studies to find out whether the products are safe and effective for approval under the act (21 U.S.C. 301 *et seq.*) or under section 351 of the PHS Act (42 U.S.C. 262). All studies of new drug and biological products must be conducted under the FDA's investigational new drug (IND) procedures and studies of medical devices must be conducted under the investigational device exemption (IDE) procedures. Studies of approved products to evaluate new orphan indications are also acceptable; however, these also must be conducted under an IND or IDE to support a change in labeling. (See section V.B of this document (Program Review Criteria) for important requirements about IND/IDE status of products to be studied under these grants.)

Studies proposed for the larger grants ($300,000) must be continuing in phase 2 or phase 3 of investigation. Phase 2 trials include controlled clinical studies conducted to evaluate the effectiveness of the product for a particular indication in patients with the disease or condition and to determine the common or short-term side effects and risks associated with it. Phase 3 trials gather more

information about effectiveness and safety that is necessary to evaluate the overall risk-benefit ratio of the product and to provide an acceptable basis for physician labeling. Studies proposed for the smaller grants ($150,000) may be phase 1, 2, or 3 trials. Budgets for all years of requested support may not exceed the $300,000 or $150,000 direct cost limit, whichever is applicable.

Applications must propose a clinical trial of one therapy for one indication. The applicant must provide supporting evidence that the product to be studied is available to the applicant in the form and quantity needed for the clinical trial. The applicant must also provide supporting evidence that the patient population has been surveyed and reasonable assurance that the necessary number of eligible patients is available for the study. Funds may be requested in the budget to travel to FDA for meetings with reviewing division staff about the progress of product development.

II. Human Subject Protection and Informed Consent

A. Protection of Human Research Subjects

All institutions engaged in human subject research supported by the Department of Health and Human Services (DHHS) must file an ''assurance'' of protection for human subjects with the Office for Human Research Protection (OHRP) (45 CFR part 46). Applicants may wish to visit the OHRP Internet site at http://ohrp.osophs.dhhs.gov for guidance on human subjects issues. The requirement to file an assurance includes both ''awardee'' and collaborating ''performance site'' institutions. Awardee institutions are automatically considered to be engaged in human subject research whenever they receive a direct DHHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award. The awardee is also responsible for ensuring that all collaborating institutions engaged in the research hold an approved assurance prior to their initiation of the research. No awardee or performance site may spend funds on human subject research or enroll subjects without the approved and applicable assurance(s) on file with OHRP.

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

B. Key Personnel Human Subject Protection Education

The awardee institution should ensure that all key personnel receive appropriate training in their human subject protection responsibilities. Within 30 days of award, the principal investigator should provide a letter describing the human subjects protection training for each individual identified as ''key personnel'' in the proposed research. Key personnel include all principal investigators, co-investigators, and performance site investigators responsible for the design and conduct of the study. The description of training should be submitted in a letter that includes the names of the key personnel the title of the education program completed by each named personnel, and a one-sentence description of the program. This letter should be signed by the principal investigator and co-signed by an institution official and sent to the Grants Management Office. OPD does not prescribe or endorse any specific education programs. Many institutions already have developed educational programs on the protection of research subjects and have made participation in such programs a requirement for their investigators. Other sources of appropriate instruction might include the online tutorials offered by the Office of Human Subjects Research, National Institutes of Health (NIH) at http://ohsr.od.nih.gov/ and by OHRP at http://ohrp.osophs.dhhs.gov/educmat.htm. Also, the University of Rochester has made available its training program for individual investigators. Their manual can be obtained through Centerwatch, Inc., at http://www.centerwatch.com.

C. Informed Consent

Consent forms, assent forms, and any other information given to a subject, should be sent with the grant application. Information given to the subject or his or her representative must be in language the subject or representative can understand. No informed consent, whether verbal or written, may include any language through which the subject or representative waives any of the subject's legal rights, or by which the subject or representative releases or appears to release the investigator, the sponsor, or the institution or its agent from liability. If a study involves both adults and children, separate consent forms should be provided for the adults and the parents or guardians of the children.

D. Elements of Informed Consent

The elements of informed consent are stated in the DHHS regulations at 45 CFR 46.116 and 21 CFR 50.25 as follows:

1. Basic Elements of Informed Consent

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

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

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

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

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

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

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

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

(h) A statement that participation is voluntary, that refusal to take part will

involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may stop participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Other Elements of Informed Consent

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

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

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

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

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly ending of participation by the subject.

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

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

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

III. Reporting Requirements

The original and two copies of the annual Financial Status Report (FSR) (SF–269) must be sent to FDA's grants management officer within 90 days of the budget period end date of the grant. Failure to file the FSR in a timely fashion will be grounds for suspension or termination of the grant. For continuing grants, an annual program progress report is also required. 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. This includes, but is not limited to, submission of an annual report to the proper regulatory review division within FDA. Failure to meet regulatory requirements will be grounds for suspension or termination of the grant.

The program project officer will monitor grantees quarterly and will prepare written reports. The monitoring may be in the form of telephone conversations or e-mail between the project officer/grants management specialist and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these reports will be recorded in the official grant file and may be available to the grantee on request consistent with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions, 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.

IV. Mechanism of Support

A. Award Instrument

Support will be in the form of a grant. All awards will be subject to all policies and requirements that govern the research grant programs of PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program. The NIH's modular grant program does not apply to this FDA grant program. All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the act (21 U.S.C. 355, 360b, and 360e), section 351 of the PHS Act (42 U.S.C. 262), and regulations issued under any of these sections.

B. Eligibility

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

C. 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 one year, a second or third year of noncompetitive continuation of support will depend on: (1) Performance during the preceding year; (2) Federal funds availability; and (3) compliance with regulatory requirements of the IND/IDE.

D. Funding Plan

The number of studies funded will depend on the quality of the applications received and the Federal funds available to support the projects. Before an award will be made, OPD will confirm the active status of the protocol under the IND/IDE. If the protocol is under FDA clinical hold for any reason, no award will be made. Also, if the IND/IDE for the proposed study is not active and in complete regulatory compliance, no award will be made. Documentation of IRB approvals for all performance sites must be on file with the Grants Management Office, FDA (address above), before research can begin at that site.

V. Review Procedure and Criteria

A. Review Method

Grants management and program staff will first review all applications sent in response to this request for application (RFA). A responsive application is defined as being in compliance with the following program review criteria. Applications found to be nonresponsive will be returned to the applicant without further consideration.

B. Program Review Criteria

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

1. The application must propose a clinical trial intended to provide safety and/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 protocol proposed in the grant application must already be under an active IND or IDE (not under review or on hold) before the grant application deadline, as described below:

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

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

(c) The applicant should submit an IND/IDE verification with the application. The verification includes the IND/IDE number, the date the subject protocol was submitted to FDA for the IND/IDE review, the IND serial number (if known), and a statement that the IND/IDE contains the same protocol as proposed in the grant application and that this IND/IDE is active (not under review or on hold).

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

(e) 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.

(f) Studies of already approved products, evaluating new orphan indications, are also subject to these IND/IDE requirements.

(g) 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) as stated in this request for applications. Any application received that requests support over the maximum amount allowable for that particular study will be considered nonresponsive.

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

7. 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.

8. Applicants must follow guidelines named in the PHS 398 (Rev. 5/01) grant application kit.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Consultation with the proper FDA review division may also occur during this first review to determine whether the proposed study will provide data that could result in or contribute to product approval. Responsive applications will be subject to a second review by a National Advisory Council for concurrence with the recommendations made by the first-level reviewers, and funding decisions will be made by the Commissioner of Food and Drugs.

C. Scientific/Technical Review Criteria

The ad hoc expert panel will provide the first review. The application will be judged on the following scientific and technical merit criteria:

1. The soundness of the rationale for the proposed study.

2. The quality and appropriateness of the study design to include the rationale for the statistical procedures.

3. The statistical justification for the number of patients chosen for the study, based on the proposed outcome measures and the appropriateness of the statistical procedures for analysis of the results.

4. The adequacy of the evidence that the proposed number of eligible subjects can be recruited in the requested timeframe.

5. The qualifications of the investigator and support staff, and the resources available to them.

6. The adequacy of the justification for the request for financial support.

7. The adequacy of plans for complying with regulations for protection of human subjects.

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

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

D. Award Criteria

Resources for this program are limited. Therefore, should FDA approve two or more applications that propose duplicative or similar studies, FDA will support only the study with the best score.

VI. 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 the PHS 5161–1 (Rev. 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura Stephanos (address above). State and local governments may use the PHS 398 (Rev. 5/01) application form instead of the PHS 5161–1. The application receipt dates are October 17, 2001, and March 5, 2002. Other than evidence of final IRB approval, no material will be accepted after the receipt date. The mailing package and item two of the application face page should be labeled, ''Response to RFA–FDA–OPD–2002.'' 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 RFA will be considered a request to withdraw the previous application. Resubmissions are treated as new applications; therefore, the applicant may wish to address the issues presented in the summary statement from the previous review, and include a copy of the summary statement itself.

VII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, from 8 a.m. to 4:30 p.m., Monday through Friday, by the established receipt dates. Applications will be considered received on time if sent or mailed by the receipt dates as shown by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants

should note the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.) Do not send applications to the Center for Scientific Research (CSR), NIH. Any application sent to NIH that is then forwarded to FDA and received after the applicable due date will be judged nonresponsive and returned to the applicant. Application forms can be found on the Internet (address http://www.fda.gov/orphan). However, as noted above, do not mail applications to NIH. Applicants should know FDA does not adhere to the page limits or the type size and line spacing requirements imposed by NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/01). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed except for the receipt dates and the mailing label address. Do not send applications to the CSR, NIH. Applications from State and local governments may be sent on Form PHS 5161–1 (Rev. 7/00) or Form PHS 398 (Rev. 5/01). The face page of the application should reflect the request for applications number RFA–FDA–OPD–2002. The title of the proposed study should include the name of the product and the disease/disorder to be studied and the IND/IDE number. The format for all following pages of the application should be single-spaced and single-sided. Data information included in the application will generally not be publicly available prior to the funding of the application. Data included in the application may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61) even after funding has been granted. To designate information that an applicant believes to be trade secret or confidential commercial information that remains exempt from disclosure after funding, sponsors should use the legend below. Information collection requirements requested on Form PHS 398 (Rev. 5/01) has been sent by the PHS to the Office of Management and Budget (OMB) and was approved and assigned OMB control number 0925–0001.

C. Legend

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

Dated: August 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21622 Filed 8–22–01; 2:46 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 10, 2001, from 9 a.m. to 6 p.m., and September 11, 2001, from 8 a.m. to 6 p.m.

Location: Marriott Hotel, Salons D, E, and F, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact: Megan Moynahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 171, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 10, 2001, the committee will discuss, make recommendations, and vote on two premarket approval applications (PMAs) for septal occluders. On September 11, 2001, the committee will discuss, make recommendations, and vote on two PMAs, one for a surgical sealant and one for a biological glue. Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at http://www.fda.gov/cdrh/panelmtg.html. Material for the September 10, 2001, meeting will be posted on September 7, 2001; material for the September 11, 2001, meeting will be posted on September 10, 2001.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 31, 2001. On both days, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of each topic and for approximately 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 31, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

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

Dated: August 20, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–21528 Filed 8–24–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: September 5, 2001; 9:00 a.m.–1:00 p.m.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

The full Commission will meet on Wednesday, September 5, from 9:00 a.m. to 1:00 p.m. The public can join the meeting in person at the address listed above or by Audio Conference Call by calling 1–888–323–2715 and providing the following information: