other for-profit; *Number of Respondents:* 7000; *Total Annual Responses:* 7000; *Total Annual Hours:* 583.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: May 22, 2003.

Dawn Willinghan,

CMS Reports Clearance Officer, Division of Regulations Development and Issuances, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 03–13666 Filed 5–30–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Innovative Food Safety Projects; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of an innovative food safety program. The agency will have approximately $300,000 available for this program in fiscal year (FY) 2003. FDA anticipates making at least six awards, not to exceed $50,000 (direct and indirect costs combined) per award per year. Support of these grants will be for 1 year. The number of grants funded will depend on the quality of the applications received and the availability of Federal funds to support the grant. These grants are not intended to fund food inspections.

DATES: Submit applications by July 17, 2003.

ADDRESSES: Application kits are available from, and completed applications should be submitted to Cynthia M. Polit, Grants Management Office (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cpolit@oc.fda.gov*. Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20852. Application forms PHS–5161–1 (7/00) are available via the Internet at *http://www.psc.gov/forms* (revised 7/00). **NOTE**: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Cynthia M. Polit (see **ADDRESSES**).

Regarding the programmatic aspects of this notice: Paul M. Raynes, Division of Federal-State Relations (HFC–150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, e-mail: *dfsr@ora.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA will support projects covered by this notice under Title XVII of the Public Health Service Act (42 U.S.C. 1702). FDA's project program is described in the Catalog of Federal Domestic Assistance, No. 93.245, and applicants are limited to food safety regulatory agencies of State, local, and tribal governments.

FDA urges applicants to submit work plans that address specific objectives of ''Healthy People 2010.'' Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, volumes 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 foreign) as well as on the Internet at *http://www.health.gov/healthypeople*. Internet viewers should proceed to ''Publications.''

The Public Health Service (PHS) strongly encourages all award 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.

II. Background

The Office of Regulatory Affairs (ORA) is the inspection component of FDA and utilizes approximately 1,600 investigators and inspectors to oversee the country's approximately 95,000 FDA-regulated businesses. These investigators inspect more that 15,000 facilities a year. In addition to their efforts under the standard inspection program, they conduct special investigations and food inspection recall audits, perform consumer complaint inspections, and collect samples of regulated products. FDA has relied on the States in assisting with these activities through formal contracts, partnership agreements, and other arrangements. Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the demands on both the agency and the States have increased. Procedures need to be reviewed and innovative changes made that will increase effectiveness and efficiency and conserve resources. ORA will continue to support food safety programs by: (1) Effectively and efficiently ensuring compliance of regulatory products, and (2) providing high quality, science-based work that results in maximizing consumer protection. Since it's inception in FY 1999 this program has been extremely successful and generated significant projects benefiting State and local governments, FDA, and the general public. To view past awards view the ORA Web site at *www.fda.gov/ora/fed_state/Innovative_Grants.html*.

In partnership with our State and local food safety agencies, FDA will continue to develop innovative food safety programs that would be utilized nationally by State and local food safety regulatory agencies. Even though the American food supply is among the safest in the world, 76 million Americans become ill each year from the food they consume, and approximately 5,000 Americans a year, primarily the very young and elderly, die as a result. The goal of our food safety programs is to further reduce the incidence of foodborne disease to the greatest extent possible. Innovative food safety programs that are developed at the State and local levels and have national implication could enhance programs that are developed at the Federal level.

A. Project Goals, Definitions, and Examples

The specific goal of this program is to complement, develop, or improve State and local food safety programs that could be applied to food safety

programs nationwide. Examples of food safety projects are the retail food program; the egg, milk, and shellfish safety programs; and, State food safety laboratories. Applications that address one of the food safety projects and fulfill the following specific project objectives will be considered for funding.

Each application must address only one project. Applicants may apply for more than one project area, but must submit a separate application for each project. These grants are not to be used to fund or conduct food inspections for food safety regulatory agencies. For example, applications relating to the Retail Food Program area should be applicable to program improvement processes for FDA's Draft ''Recommended National Retail Food Regulatory Program Standards'' (*http://vm.cfsan.fda.gov/~dms/ret-toc.html*) (see review criteria).

There are three key project areas identified for this effort:

1. Inspection

One key project area is the development of innovative regulatory inspection methods or techniques for the inspection process of various food establishments in order to improve effectiveness and efficiency. Innovative Regulatory Program Methodology projects must demonstrate an effect on factors that contribute to foodborne illness in all, or a segment of, food industry programs. For example, projects could address key elements from the draft entitled ''Recommended National Retail Food Regulatory Program Standards,'' such as the 5 Food Code Interventions (management knowledge; employee health; hands as a vehicle of contamination; time/temperature relationships; and consumer advisory), or the 5 Centers for Disease Control and Prevention (CDC) Risk factors (improper holding temperature; inadequate cooking; contaminated equipment; unsafe source; and poor personal hygiene). Other examples of projects in this area could include prevention and control of *Listeria monocytogenes* in retail and foodservice environments and projects that address shell egg safety, such as refrigeration, safe handling, or labeling. The goal of these projects should be to achieve efficient and effective compliance with regulations that affect factors that contribute to foodborne illness.

2. Education and Health Information Dissemination

Another key project area is the development of innovative education projects and materials for State and local food safety regulatory officials that foster consistency and uniform application of State and local food regulations. These education projects and/or materials must be reproducible by other State and local food safety regulatory agencies. These projects may incorporate concurrent education of both State and local food safety regulatory agencies and the food industry.

3. State Laboratories

FDA recognizes that there are a number of new technologies and test methods that may be applicable to chemical and/or microbiological food analyses. FDA's regulation of a wide range of food commodities requires the validation of new test methods in a variety of food matrices. State/local food testing laboratory validation of test methods will provide the Federal, State, and local food safety agencies with invaluable information with respect to the methods' feasibility and applicability. State laboratories should identify areas in food testing (chemical and/or biological) that would enhance their program activities and provide alternative analytical capabilities for Federal and local food safety officials.

Requirements For State Laboratories Projects:

The applicant must include the following in the grant application:

1. The applicant must identify rapid test method/technique proposed for validation study. Please note that this is NOT research; it is a single lab validation of food test methods/techniques with already existing data that warrants further investigation. Selection of test method technology must fall under the following categories:

- AOAC official method with foods and food commodities that have not been previously validated;
- Non-AOAC official method, i.e., State lab method;
- New technology or method with single lab validation for a particular food and analyte (validation data must be submitted).

2. The applicant must include at least 4 food matrices for each validation study. Food matrices selected should benefit State program activities in addition to providing Federal and local agencies with alternative analytical capabilities.

3. The applicant must identify the microbiological or chemical test method protocol, including laboratory equipment and personnel needed for each validation study. Copies of the complete methods for the validation study must be included.

4. The applicant must cite and incorporate into a protocol the single-laboratory method validation guidelines (i.e., AOAC) for both chemical and microbiological validations studies.

5. The applicant must also provide a scientific review of the literature pertaining to the rapid test.

6. The applicant must agree to provide a written report on the laboratory findings, including all the above materials and appropriate documentation which will be reviewed by the FDA Division of Field Science (DFS) before being recommended to other State/local food safety agencies.

B. Applicability

All grant application projects that are developed at State, local, and tribal levels MUST have national implication or application that can enhance Federal, State, and local food regulatory programs and are likely to reduce factors that cause foodborne illness. At the discretion of FDA, successful project formats will be made available to interested Federal, State, local, and tribal food safety regulatory agencies. No grant will be awarded for projects that do not support the FDA Food Code.

FDA reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use, and to authorize others to use, for Federal Government purposes: (1) The copyright in any work developed under a grant, subgrant or contract under a grant or subgrant; and (2) any rights of copyright to which a grantee, subgrantee, or a contractor purchases ownership with grant support (45 CFR 92.34).

III. Reporting Requirements

Semiannual progress reports as well as a final program progress report and a final financial status report (FSR) (SF–269) are required. The grantee must submit an original FSR and two copies to FDA's Grants Management Officer within 90 days of the expiration date of the grant. The final program progress report must provide full written documentation of the project, copies of any results, as described in the grant application, and an analysis and evaluation of the results of the project. The documentation must be in a form and contain sufficient detail such that other State and local food safety regulatory agencies could reproduce the final project.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least semiannually by the project officer. Project monitoring may also be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator and/or a

site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be recorded in the official file and may be available to the recipient upon request.

IV. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of a grant. These grants will be subject to all policies and requirements that govern the project grant programs of FDA, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 also apply to this program and are implemented through Department of Health and Human Services regulations at 45 CFR part 100. Executive Order 12372 sets up a system for State and local government review of applications for Federal financial assistance. Applicants (other than Federally recognized Indian tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert the SPOC to the prospective application(s) and to receive any necessary instructions on the State's review process. A current listing of SPOCs is included in the application kit. The SPOC should send any State review process recommendations to the FDA administrative contact (see **ADDRESSES**). The due date for the State process recommendations is no later than 60 days after the deadline date for the receipt of applications. FDA does not guarantee to accommodate or explain SPOC comments that are received after the 60 day cutoff.

B. Eligibility

This grant program is only available to State, local, and tribal government food regulatory agencies. (See SPOC requirements stated in section IV.A of this document).

C. Length of Support

The length of support will be for 1 year from date of award.

V. Review Procedure and Criteria

All applications submitted in response to the Request for Applications (RFA) will first be reviewed by grants management and program staffs for responsiveness. Responsiveness is defined as submission of a complete application with original signatures on or before the required submission date as listed above. If applications are found to be nonresponsive, they will be returned to the applicant without further consideration. An application will be considered nonresponsive if any of the following circumstances are not met: (1) If it is received after the specified receipt date; (2) if the total dollar amount requested from FDA exceeds $50,000; (3) if all required original signatures are not on the face, assurance or certification pages of the application; (4) if there is no original signature copy; (5) if it is illegible; (6) if the material presented is insufficient to permit an adequate review; (7) if the application demonstrates an inadequate understanding of the intent of the RFA; (8) if the application is determined to be essentially similar to projects that have been funded in the past; (9) if for any reason the results of the project, including computer software, cannot be made available to other State, local, and tribal food regulatory agencies. Applicants are encouraged to check the list of projects that received funding in prior years under this program on the Internet at *http://www.fda.gov/ora/fed__state/Innovative__Grants.html*.

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. Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Other award criteria will include availability of funds and overall program balance in terms of geography. Final funding decisions will be made by the FDA Commissioner or his designee.

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their applications. All questions of a technical or programmatic nature must be directed to the ORA program staff (Paul Raynes) and all questions of an administrative or financial nature must be directed to the grants management staff (Cynthia Polit).

Applications will be given an overall score and judged based on all of the following criteria:

- Application budgets must remain within the $50,000 cap for combined direct and indirect costs. Applications exceeding this dollar amount will be returned as nonresponsive.
- Applications must provide in DETAIL, a sound rationale and appropriate grant design to address the objectives of the RFA.
- The project MUST be generic enough in nature to be used by other State, local, and tribal food regulatory agencies.
- Applications must include a detailed explanation of the desired goals and outcomes of the project.
- For applications relating only to the Retail Food Program, the outcome of the project should be applicable to the program improvement process for FDA's Draft ''Recommended National Retail Food Regulatory Program Standards.'' These standards will serve as a guide to the regulatory retail food program. The standards apply to the operation, management, and promotion of a regulatory retail food program focused on the reduction of risk factors known and suspected to cause foodborne illness. The FDA Draft ''Recommended National Retail Food Regulatory Program Standards'' can be found on the Internet site at *http://vm.cfsan.fda.gov/~dms/ret-toc.html* or contact your local FDA Regional Retail Food Specialist from the list provided in the application packet.
- Applications must include a full description of the project design, a detailed implementation plan, methods of execution, and a timeline for completion. The application must include a detailed description of measures of effectiveness and a description of the source documents or data collection methods for establishing the baseline for measurement.
- Applications must address the adequacy of facilities, equipment, databases and support services and the expertise of project staff needed for the project.
- Applicants and applicant's subgrantees and subcontractors must ensure that any projects developed in whole or in part with Federal funds may be made available to other State, local, and tribal food regulatory agencies by FDA or its agents. Copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.
- Laboratory grant applications must meet all the requirements in the key project areas: State laboratories (see section II.A. 3 of this document).

VI. Submission Requirements

The original and two copies of the completed Grant Application Form PHS–5161–1 (Revised 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Cynthia M. Polit (see **ADDRESSES**). The application receipt date is July 17, 2003. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday. No supplemental or addendum material will be accepted after the receipt date.

The outside of the mailing package and item 2 of the application face page should be labeled ''Response to RFA-

FDA-ORA–03–Project I (Inspection)'' or ''RFA-FDA-ORA–03–Project II (Education and Health Information Dissemination) or ''RFA-FDA-ORA–03–Project III (State Laboratories).'' You must submit only one project application (an original and two copies) per package.

VII. Method of Application

A. Submission Instructions

You must submit each application under separate cover. Do not submit more than one application (original with 2 copies) per envelope. Applications will be accepted during working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced 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 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.

Do not send applications to the Center for Scientific Research (CDR), NIH. Any application sent to NIH that is then forwarded to FDA and not received in time for orderly processing will be deemed unresponsive and returned to the applicant. Instructions for completing the application are included in Form PHS–5161–1. FDA is unable to receive applications via the Internet.

B. Format for Application

You must submit the application on Grant Application Form PHS 5161–1 (Rev 7/00). All of the instructions for the enclosed Standard Form 424 (SF424) should be followed using the nonconstruction application pages. A properly formatted sample application for the grant can be accessed on the Internet at *http://www.fda.gov/ora/fed__state/Innovative__Grants.html*. Applications may be considered nonresponsive if not submitted in the proper order.

The face page of the application should indicate ''RFA–FDA–ORA–03–Project I (Inspection),'' or ''RFA–FDA–ORA–03–Project II (Education and Health Information and Dissemination)'' or ''RFA–FDA–ORA–03–Project III (State laboratories).''.

Data and information included in the application, if identified by the applicant as trade secret will be given treatment as such to the extent permitted by the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on PHS Form 5161–1 were approved and issued under the Office of Management and Budget Circular A–102.

Dated: May 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13594 Filed 5–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91D–0407]

Medical Devices; Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA.'' This document describes a means by which resorbable calcium salt bone void filler devices may comply with the requirement for special controls. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to classify the resorbable calcium salt bone void filler device into class II (special controls).

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Nadine Y. Sloan, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 7, 2002 (67 FR 5753), FDA published a proposed rule to classify the resorbable calcium salt bone void filler device into class II (special controls). FDA identified the draft guidance document entitled ''Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device: Draft Guidance for Industry and FDA'' as the special control capable of providing reasonable assurance of safety and effectiveness for these devices.

Interested persons were invited to comment on the draft guidance by May 8, 2002. FDA received three comments. These comments were supportive of the guidance document and made suggestions on the guidance's content. Two of the comments also requested clarification of the scope and the risks in the guidance document. FDA considered the comments and revised the guidance document accordingly. We also clarified our labeling recommendations.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the resorbable calcium salt bone void filler device. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a resorbable calcium salt bone void filler device will need to