effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market. If manufacturers were not required to provide this information to FDA, FDA's ability to ensure that recalls are conducted properly would be greatly impaired.

In the **Federal Register** of February 23, 1999 (64 FR 8832), the agency requested comments on the proposed collections of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	3	1	3	4,500	13,500
107.240	3	1	3	1,482	4,446
107.250	3	1	3	120	360
107.260	3	1	1	650	650
Total					18,956[2]

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Due to clerical error, the reporting burden hours for §§ 107.230, 107.240, 107.250, and the total burden hours that appeared in a notice issued in the FEDERAL REGISTER of February 23, 1999 (64 FR 8832), were incorrect. Table 1 of this document contains the correct estimates.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been three recalls in the last 3 years, or one recall annually.

Dated: May 10, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–12283 Filed 5–14–99; 8:45 am]

BILLING CODE 4160–01–F

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), Office of Regulatory Affairs (ORA), Division of Federal-State Relations, is announcing the availability of grant funds for the support of innovative food safety pilot programs. Approximately $300,000 will be available in fiscal year 1999. FDA anticipates making six to eight awards, not to exceed $50,000 (direct and indirect costs combined) per award. 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. This is a pilot grant program which, if successful, may lead to other grant programs in the future. These grants are not intended to fund or conduct food inspections.

DATES: Submit applications by July 1, 1999. If the closing date falls on a weekend or on a holiday, the date of submission will be extended to the following workday.

ADDRESSES: Application forms are available from, and completed applications should be submitted to Robert L. Robins, Chief Grants Management Officer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7185, e-mail ''rrobins@oc.fda.gov''. (Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20852.)

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Robert L. Robins (address above).

Regarding the programmatic aspects of this notice: Richard H. Barnes or Glenn Johnson, Division of Federal-State Relations, Office of Regulatory Affairs, Food and Drug Administration (HFC–150), 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, Internet site: ''www.fda.gov/ora/fed—state''.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA will support projects covered by this notice under section 1701 (300u) of the Public Health Service Act (42 U.S.C. 241). 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 and local governments. 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.

PHS urges applicants to submit work plans that address specific objectives of ''Healthy People 2000.'' Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, stock No. 017–0010–0474–0) through Superintendent of Documents, Government Printing Office,

Washington, DC 20402–9325, 202–512–1800.

II. Background

ORA is the inspection component of FDA and has 1,000 investigators and inspectors who cover the country's approximately 95,000 FDA-regulated businesses. These investigators and inspectors inspect more that 15,000 facilities a year. In addition to the standard inspection program, they conduct special investigations, food inspection recall audits, perform consumer complaint inspections and sample collections. In addition, FDA has relied on the States in assisting with the previously mentioned duties through formal contracts, partnership agreements, and other informal arrangements. Under the President's Food Safety Initiative (FSI), the demands on both the agency and the States will increase. Procedures need to be reviewed and innovative changes made that increase effectiveness and efficiency and conserve resources. ORA will support FSI by providing: (1) Effective and efficient compliance of regulated products; and (2) high quality, science-based work that maximizes consumer protection.

Under FSI, FDA is developing innovative food safety programs that will be utilized nationally by State and local food safety regulatory agencies. Even though the American food supply is among the safest in the world, millions of Americans are stricken by illness each year caused by the food they consume, and some 9,000 Americans a year, primarily the very young and elderly, die as a result. The goal of FSI 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 level and have national implications could enhance programs that are developed at the Federal level.

A. Project Goals, Definitions, and Examples

The specific objective of this program will be to complement, develop or improve State and local food safety programs that would have applicability to food safety programs nationwide. Applications that 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 fund or conduct food inspections for food safety regulatory agencies. Applications relating to the Retail Food Program area should be applicable to program improvement processes consistent with FDA's draft entitled ''Recommended National Retail Food Regulatory Program Standards'' (''http://www.cfsan.fda.gov/~dms/ret-toc.html'') (see review criteria).

There are four key project areas identified for this effort:

1. Inspection

Development of innovative regulatory inspection methods or techniques for the inspection of various food establishments in order to improve effectiveness and efficiency. Innovative Regulatory Program Methodology projects must demonstrate an effect on factors which 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 five major *Food Code* Interventions (management knowledge; employee health; hands as a vehicle of contamination; time/temperature relationships; and consumer advisory), or the five Centers for Disease Control and Prevention risk factors (improper holding temperature; inadequate cooking; contaminated equipment; unsafe source; and poor personal hygiene).

2. Regulation and Compliance

Development of new procedures for industry that would enhance the efficiency and effectiveness of Federal, State, and local compliance actions. Examples of projects in this area could include innovative regulation and compliance strategies for State and local food safety regulatory agencies. The goal of these projects should be to achieve efficient and effective compliance with regulations that impact contributing factors to foodborne illness.

3. Information Systems

Development of systems for collection, storage, and retrieval of data on projects that support food safety regulatory State or local programs. These systems should utilize readily available ''off the shelf'' technology systems that could be used by food safety regulatory agencies of any size.

4. Education and Health Information Dissemination

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.

B. Applicability

All grant application projects that are developed at State and local levels must have national implication or application that can enhance Federal, State, and local food regulatory programs and reduce factors that cause foodborne illness. At the discretion of FDA, successful project formats will be made available to interested Federal, State, and local food safety regulatory agencies.

III. Reporting Requirements

Quarterly progress reports as well as a Final Program Progress Report and a Financial Status Report (FSR) (SF–269) are required. An original FSR and two copies shall be submitted to FDA's Chief Grants Management Officer (address above), 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 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 quarterly 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 PHS, 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 (DHHS) 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 them to the prospective application(s) and to receive any necessary instructions on the State's review process. A current listing of SPOC's is included in the application kit. The SPOC should send any State review process recommendations to FDA's Chief Grants Management Officer (address listed above). 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 cut-off.

B. Eligibility

These grants are available to State and local government food regulatory agencies (see SPOC requirements stated previously).

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 this request for application (RFA) will first be reviewed by grants management and program staff for responsiveness. If applications are found to be nonresponsive, they will be returned to the applicant without further consideration.

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. Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence with the recommendations made by the first level reviewers. Final funding decisions will be made by the Commissioner of Food and Drugs or her designee.

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their application. All questions of a technical or programmatic nature must be directed to the ORA program staff (address above) and all questions of an administrative or financial nature must be directed to the grants management staff (address above). Applications will be given an overall score and judged based on all of the following criteria:

1. Applications relating to the Retail Food Program (''http://www.cfsan.fda.gov/~dms/ret-toc.html'') only: The outcomes of the project should be consistent with the program improvement process described in FDA's draft entitled ''Recommended National Retail Food Regulatory Program Standards'' (http://www.cfsan.fda.gov/~dms/ret-toc.html''). These standards will serve as a guide to regulatory retail food program managers for the design and management of a 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 and integration of the five major *Food Code* interventions listed in section II.A.1 of this document. The FDA draft entitled ''Recommended National Retail Food Regulatory Program Standards'' and the 1999 *Food Code* are found on the Internet site at ''http://www.cfsan.fda.gov/~dms/ret-toc.html'' or contact your local FDA Regional Retail Food Specialist from the list provided in the application packet about obtaining copies.

2. 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.

3. Applications must provide a sound rationale and appropriate grant design to address the objectives of the RFA and the project must be reproducible within the national regulatory framework.

4. Applications must include an explanation of the desired goals of the pilot project.

5. Applications must include a full description of the project design, implementation plan, methods of execution, and timeline for completion. The application must include a full description of measures of effectiveness and a description of the source documents or data collection methods for establishing the baseline for measurement.

6. Applications must address the adequacy of facilities, expertise of project staff, equipment, data bases, and support services needed for the project.

VI. Submission Requirements

The original and two copies of the completed Grant Application Form PHS–5161–1 (revised May 1996) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Robert L. Robins (address above). The application receipt date is July 1, 1999. If the receipt date falls on a weekend or on a holiday, it will be extended to the following workday. No supplemental material or addenda 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–99–Project I, Project II, Project III or Project IV.''

VII. Method of Application

A. Submission Instructions

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, National Institutes of Health (NIH). Any application that is sent to NIH, that is then forwarded to FDA and not received in time for orderly processing, will be deemed nonresponsive 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

Submission of the application must be on Grant Application Form PHS–5161–1 (revised May 1996). All instructions for the enclosed Standard Form 424 (SF–424) should be followed using the nonconstruction application pages.

The face page of the application should indicate ''RFA–FDA–ORA–99–Project I, Project II, Project III or Project IV.''

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of 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 Office of

Management and Budget Circular A–102.

C. Legend

Unless disclosure is required by the FOIA 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 page number, paragraph, etc., by the applicant as containing restricted and/or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated: May 10, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–12287 Filed 5–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4513–N–01]

Mortgagee Approval for Single Family Programs; Clarification Procedures for Terminating Origination Approval Agreements and Placement in Credit Watch Status

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: It is the longstanding policy of HUD's Federal Housing Administration (FHA) to issue periodically mortgagee letters to FHA-approved lenders to apprise the lenders of upcoming changes in FHA programs, new processing requirements, or clarification of existing procedures, among other things. The FHA has issued a mortgagee letter to advise FHA lenders that HUD/FHA will be using its regulatory authority to terminate lenders' authorization to originate single family loans or, alternatively, place lenders on Credit Watch status (an evaluation period) in geographic areas where the lender has a high rate of early defaults and claims. The FHA is publishing the contents of this mortgagee letter in the **Federal Register** for the benefit of the public.

FOR FURTHER INFORMATION CONTACT: For further information contact: the Quality Assurance Division, Office of Housing, Department of Housing and Urban Development, 451 Seventh St, SW, Room B–133, Washington, DC, 20410; telephone (202) 708–2830 (this is not a toll-free number). Persons with hearing or speech impairments may access that number via TTY by calling the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Department has the authority to address deficiencies in the performance of lenders' loans as provided in the HUD mortgagee approval regulations at 24 CFR 202.3. The latest revisions to these regulations were published as an interim rule on December 10, 1997 at 62 FR 65180 (which contains the text of the amendments) and were published as a final rule on August 17, 1998 (63 FR 44360), which was effective September 17, 1998. In the near future, HUD/FHA will systematically review mortgagees' early default and claim rates, that is, defaults (loans 90 or more days delinquent) and claims on mortgagees' loans during the initial 24 months from endorsement. HUD may place mortgagees with excessive default and claim rates on Credit Watch status or, in cases of more severe performance deficiencies, terminate mortgagees' loan origination approval authority.

Termination of Origination Approval Agreement

Approval of a mortgagee by HUD/FHA to participate in FHA mortgage insurance programs includes an Origination Approval Agreement (Agreement) between HUD and the mortgagee. Under the Agreement, the mortgagee is authorized to originate single family mortgage loans and submit them to FHA for insurance endorsement. The Agreement may be terminated on the basis of poor performance of FHA-insured mortgage loans originated by the mortgagee. The Termination of a mortgagee's Agreement is separate and apart from any action taken by HUD's Mortgagee Review Board under HUD's regulations at 24 CFR part 25.

Frequency and Scope of Reviews

Every three months, HUD will review the rate of defaults and claims on all FHA-insured single family mortgages. The review will analyze the performance of every participating mortgagee branch in each geographic area served by a HUD field office. The review will be limited to loans endorsed for insurance within the preceding 24 months.

Unacceptable Results

HUD's regulations permit HUD to terminate the Agreement with any mortgagee having a default and claim rate for loans endorsed within the preceding 24 months that exceeds 200 percent of the default and claim rate within the geographic area served by a HUD field office, and also exceeds the national default and claim rate. Mortgagees whose default and claim rates exceed both the national rate and 200% of the field office rate are at risk and may have their Agreements terminated.

Initially, HUD will focus its attention on those mortgagees showing particularly high default and claim rates. For the first review period, HUD will consider terminating the Agreement of any mortgagee whose default and claim rate exceeds both the national rate and 300% of the field office rate. HUD will notify the mortgagee, via certified mail, before terminating its Agreement.

In any one of the subsequent review periods, HUD may set the field office portion of the termination threshold at a rate other than 300% of the field office rate, but not lower than 200% of such rate. HUD will give notice of the threshold for each review period by Mortgagee Letter.

Mitigating Factors Evaluated Initially

Prior to sending a Termination notice, HUD/FHA will analyze mortgagees' portfolios of loans to determine if their poor performance is due to where they originated loans and the types of loans they originated. HUD/FHA will analyze loan types in terms of FHA's three Insurance Funds and place in terms of underserved versus served census tracts. For each of these five analyses, the mortgagee's loan performance will be compared to the Field Office average for similar loans. For example, in the first review period, if the mortgagee's rate of defaults and claims on loans in underserved census tracts does not exceed 300% of the field office's rate of defaults and claims in underserved census tracts, the mortgagee's performance is below the Termination threshold in underserved areas. Mortgagees with a performance below the Termination threshold in each of these five assessments will not receive a Termination Notice; however, they may receive a Credit Watch notice (see Credit Watch description below).

Appeal Process

HUD regulations at 24 CFR 202.3(c)2)(ii)(C) permit a mortgagee to request an informal conference with the Deputy Assistant Secretary (DAS) for Single Family Housing, or his or her designee prior to the termination of its Origination Approval Agreement. A mortgagee desiring an informal conference must submit a written request to the Docket Clerk, Departmental Enforcement Center, Legal Division, Room B–133/VALA, U.S. Department of Housing and Urban