design, data analysis, interpretation of findings, coauthorship of publications and the development and filing of patents.

VII. Review Procedure and Criteria

A. Review Method

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. Applications will be considered not responsive if they are not in compliance with sections VII.B and VIII of this document. If applications are found to be not responsive to this announcement 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 his/her designee.

B. Review Criteria

Applicants must clearly state in their application for which of the requested projects they are applying. Applications will be reviewed, and ranked. There is no assurance that awards will be made in all projects. Funding will start with the highest ranked application, and additional awards will be made based on the next highest ranking application, etc., until all available funds have been exhausted. All applications will be evaluated by program and grants management staff for responsiveness. 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 scientific nature should be directed to the CFSAN program staff, and all questions of an administrative or financial nature should be directed to the grants management staff. (See the **FOR FURTHER INFORMATION CONTACT** section at the beginning of this document for addresses.)

All applications will be reviewed and scored on the following criteria:

1. Soundness of the scientific rationale for the proposed study and appropriateness of the study design and its ability to address all of the objectives of the RFA;

2. Availability and adequacy of laboratory facilities, equipment, and support services, e.g., biostatistics computational support, databases, etc.;

3. Research experience, training, and competence of the principal investigator and support staff, and;

4. Whether the proposed study is within the budget guidelines and proposed costs have been adequately justified and fully documented.

VIII. Submission Requirements

The original and two copies of the completed grant application form PHS 398 (Rev. 4/98) or the original and two copies of 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 C. Stephanos (address above). State and local governments may choose to use the PHS 398 application form in lieu of PHS 5161–1. The application receipt date is July 5, 2001. 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–CFSAN–01–3, Project 1, 2, 3 or 4.''

IX. Method of Application

A. Submission Instructions

Applications will be accepted during normal business 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 CSR, 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 not responsive and returned to the applicant. Applications must be submitted via mail or hand delivery as stated above. FDA is unable to receive applications electronically. Applicants are advised that FDA does not adhere to the page limitations 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. 4/98) or PHS 5161–1 (Rev. 7/00). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address.

The face page of the application should reflect the request for applications number, RFA–FDA–CFSAN–01–3, Project 1, 2, 3, or 4. 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 (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001. The requirements requested on Form PHS 5161–1 were approved and assigned OMB control number 0348–0043.

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 that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: May 15, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12623 Filed 5–18–01; 8:45 am]

BILLING CODE 4160–01–S

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 (DFSR) is

announcing the availability of grant funds for the support of an innovative food safety program. Approximately $200,000 will be available in fiscal year 2001. FDA anticipates making at least four 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 or conduct food inspections.

DATES: Submit applications by July 5, 2001.

ADDRESSES: Application forms are available from, and completed applications should be submitted to Cynthia M. Polit, Grants Management Office, Food and Drug Administration (HFA–520), 5600 Fishers Lane, rm. 2129, 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 20857. Application forms PHS–5161–1 (7/00) are available via the Internet at: http://www.psc.gov/forms (revised 7/00).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Cynthia M. Polit (address and telephone number given above).

Regarding the programmatic aspects of this notice: Paul M. Raynes or Anne Hope Scott, 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. Internet site: http://www.fda.gov/ora/fed__state/default.htm.

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. FDA 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 FDA mission to protect and advance the physical and mental health of the American people.

FDA urges applicants to submit work plans that address specific objectives of ''Healthy People 2010.'' Potential applicants may obtain a copy of ''Healthy People 2010'' (full report, stock No. 017–001–00547–9) 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 some 1,100 investigators and inspectors who cover the country's approximately 95,000 FDA-regulated businesses. These investigators inspect more than 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. FDA has relied on the States in assisting with the above duties through formal contracts, partnership agreements, and other informal arrangements. Under the 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 will increase effectiveness and efficiency and conserve resources. ORA will support FSI by providing: (1) Effective and efficient compliance of regulatory products, and (2) high quality, science-based work that results in maximizing consumer protection.

Under FSI, FDA is mandated 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, millions of Americans are stricken by illness each year caused by the food they consume, and some 7,000 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 levels and have national implication 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 for FDA's draft entitled ''Recommended National Retail Food Regulatory Program Standards'' (http://vm.cfsan.fda.gov/dms/ret-toc.html) (see review criteria).

There are two key project areas identified for this effort:

1. Inspection

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 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 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). Other examples of projects in this area could include prevention and control of *Listeria monocytogenes* in retail and food service 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 impact contributing factors to foodborne illness.

2. 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. No grant will be awarded for projects that do not support the FDA Food Code.

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. An original FSR and two copies shall be submitted 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 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 duly 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 (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 SPOCs is included in the application kit. The SPOC should send any State review process recommendations to FDA's administrative contact (address listed above). The due date for the State process recommendations is no later than 60days 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

This grant program is only available to State and local government food regulatory agencies and federally recognized Indian tribal governments. (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 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. An application will be considered nonresponsive if any of the following criteria are not met: (1) If it is received after the specified receipt date; (2) if the total dollar amount requested exceeds $50,000; (3) if all required signatures are not on the face page or assurance 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; or (7) if the application demonstrates an inadequate understanding of the intent of the RFA.

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. 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 his/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 ORA's 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://vm.cfsan.fda.gov/dms/ret-toc.html) only: The outcomes of the project should be applicable to program improvement process for FDA's draft entitled ''Recommended National Retail Food Regulatory Program Standards'' (http://vm.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 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. FDA's draft entitled ''Recommended National Retail Food Regulatory Program Standards'' is 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.

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 in detail, a sound rationale and appropriate grant design to address the objectives of RFA and the project must be reproducible within the national regulatory framework.

4. Applications must include a detailed explanation of the desired goals and outcomes of the project.

5. Applications must include a full description of the project design, a detailed implementation plan, methods of execution, and 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.

6. Applications must address the adequacy of facilities, expertise of project staff, equipment, databases, 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 7/00) for State and local governments, with copies of the

appendices for each of the copies, should be delivered to Cynthia M. Polit (address above). The application receipt date is July 5, 2001. If the receipt date falls on a weekend, or if the date falls on a holiday, the date of submission 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–01–Project I'' or ''RFA–FDA–ORA–01–Project II.'' Submit only one project application (an original and two copies) per package.

VII. Method of Application

A. Submission Instructions

Each application must be submitted under separate cover. Do NOT submit more than one application (with 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, 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 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 Internet.

B. Format for Application

Submission of the application must be on grant application form PHS 5161–1 (revised 7/00). 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–01–Project I,'' or ''RFA–FDA–ORA–01–Project II.''

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 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 15, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12626 Filed 5–18–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0103]

Issues Associated With the Intersection of 180-Day Generic Drug Exclusivity and Pediatric Exclusivity; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing the public docket identified in brackets in the heading of this document to receive comments related to the interpretation of provisions of the Federal Food, Drug, and Cosmetic Act (the act) and regulations governing the intersection of 180-day generic drug exclusivity and pediatric exclusivity. To date, there has not been a situation where pediatric exclusivity and 180-day generic exclusivity have actually overlapped. However, FDA has received a large number of inquiries about its interpretation of these provisions and, therefore, is establishing this docket to give the public an opportunity to comment on these issues.

DATES: Submit written or electronic comments by June 20, 2001.

ADDRESSES: Submit electronic comments to http://www.fda.gov/ohrms/dockets/default.htm. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5468, FAX 301–594–5493.

SUPPLEMENTARY INFORMATION:

I. Background

Recently FDA has been asked to evaluate the intersection of 180-day generic drug exclusivity and pediatric exclusivity, specifically with respect to whether the exclusivity periods should run concurrently or consecutively. FDA has received written correspondence and telephone inquiries from pharmaceutical firms, organizations, individuals, and members of Congress concerning FDA's interpretation of these provisions. FDA is seeking broader public comment on the intersection of these two statutory provisions.

The 180-day generic drug exclusivity provision was created by the 1984 Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Amendments), enacted on September 24, 1984. This provision, contained in section 505(j)(5)(B)(iv) of the act (21 U.S.C. 355(j)(5)(B)(iv)), provides an incentive for generic drug applicants to challenge innovator patent claims and thereby speed the entry of generic competition onto the market. This benefit is available to the first abbreviated new drug application (ANDA) received that is a substantially complete application that contains a ''paragraph IV'' certification. This type of certification states the ANDA applicant's belief that a patent listed for the innovator drug is invalid or unenforceable or that the ANDA product seeking approval will not infringe a listed patent. Under the terms of the statute, 180-day generic drug exclusivity is triggered by and begins to run from either: (1) A court decision finding the challenged patent invalid, unenforceable, or not infringed; or (2) the date of first commercial marketing of the ANDA drug product, whichever is earlier. During the 180-day generic drug exclusivity period, FDA is prohibited