

assurance that awards will be made in each of the four project categories.

FDA will support the research studies covered by this notice under section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

FDA is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national effort to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the "Healthy People 2010" objectives, vols. I and II, for \$70 per set, (\$87.50 foreign) SN/017-000-00550 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 (\$23.50 foreign). This publication is also available on the Internet at <http://health.gov/healthypeople> under "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. Research Goals and Objectives

Proposed projects designed to fulfill the specific objectives of any one of the following requested projects will be considered for funding. Applications may address only one project and its objectives per application. However, applicants may submit more than one application for more than one project. In all of the following projects, CFSAN wants to promote the development of improved techniques for either the detection, control, or analysis of microbiological agents, toxins, and chemicals in food or cosmetics. None of the four projects should involve human research subjects. The projects and their objectives are as follows:

### A. Project 1

Develop food security rapid screening analytical methods capable of detecting 100 to 10,000 microbial pathogens/g of food, without pregrowth or selective enrichment and a total elapsed time of less than 6 hours (sample preparation time included). These methods should be immunoassay-based techniques that require a minimum of laboratory-based equipment and are capable of being reproducibly and accurately executed by a trained, bachelor of science-level laboratory technician.

### B. Project 2

Develop PCR-based methods for the purpose of providing rapid, confirmatory identification of microbial pathogens that are usually not associated with food and foodborne illness. Methods must work directly in association with the food without pregrowth or selective enrichment, and they must provide a level of sensitivity of 100 organisms or less per g of food sample. The research approach should focus on providing complete protocols. The protocols must describe food sample preparation methods that are to be used in conjunction with the PCR-based identification protocols. Additionally, methods must be compatible with a wide variety of foods or broad food groups. Such groups may be artificially defined by a variety of food properties, such as origin, physical or chemical characteristics, or the method of preparation or manufacture.

### C. Project 3

Develop rapid screening methods capable of detecting a broad range of nontraditional chemical and toxin adulterants. These methods should be either kit-based or rely upon a minimum amount of instrumentation, to readily permit rapid deployment and field program use. Methods should rely upon a minimum amount of sample preparation and be usable with broad categories of food, such as high versus low fat content, high versus low water content, or high versus low protein or carbohydrate content. Sensitivities of proposed detection methods should target the acceptable daily intake or the tolerable daily intake for the specific target analytes.

### D. Project 4

Develop improved equipment, software, procedures, and/or methods for the determination of radionuclide contamination in foods. Of particular interest are reductions of analysis time, increases in portability, simplified procedures, and improved methodology for rapid determination of alpha- and beta-emitting radionuclides.

## III. Mechanism of Support

### A. Award Instrument

Support for this program will be in the form of cooperative agreements. These cooperative agreements will be subject to all policies and requirements that govern the research grant programs of the 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 modular grant

program does not apply to this FDA program.

### B. Eligibility

These cooperative agreements 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 awards. Organizations described in section 501(c)(4) of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive awards.

### C. Length of Support

Projects may take up to a maximum of 3 years for their completion. The amount of time that will be allocated for the completion of each individually approved and funded research project will be made commensurate with the research approach and methodology being proposed.

## IV. Reporting Requirements

Annual Financial Status Reports (FSRs) (SF-269) are required. An original FSR and two copies shall be submitted to FDA's Grants Management Officer (see **ADDRESSES** section) as indicated by the timeline noted in the Notice of Grant Award. Failure to file the FSR on time may be grounds for suspension or termination of the agreement. Program Progress Reports will be required quarterly and will be due 30 days following each quarter of the applicable budget period. The final quarterly report will serve as the annual report and will be due 90 days after the budget expiration date. The recipient will be advised of the suggested format for the Program Progress Report at the time an award is made. In addition, the principal investigator will be required to present the progress of the study at an annual FDA extramural research review workshop in the Washington, DC metropolitan area. Travel costs for this requirement should be specifically requested by the applicant as part of the application. A final FSR, Program Progress Report, and Invention Statement must be submitted within 90 days after the expiration of the project period, as noted on the Notice of Grant Award.

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