Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Reliability Study Group	39	2	3	234
Validity Study Group	115	1	3	345
Total				579

4. The National Death Index (NDI) (0920–0215)—Extension—A service of the National Center for Health Statistics (NCHS), that assists health and medical researchers to determine the vital status of their study subjects. The NDI is a national data base containing *identifying* death record information submitted annually to NCHS by all the state vital statistics offices, beginning with deaths in 1979. Searches against the NDI file provide the states and dates of death and the death certificate numbers of deceased study subjects. With the recent implementation of the NDI Plus service, researchers now have the option of also receiving cause of death information for deceased subjects, thus reducing the need to request copies of death certificates from the states. The NDI Plus option currently provides the ICD–9 codes for the underlying and multiple causes of death for the years 1979–1996. The five administrative forms are completed by health researchers in government, universities, and private industry in order to apply for NDI services and to submit records of study subjects for computer matching against the NDI file. The total cost to respondents is estimated at $5,685.

Respondents	Number of respondents	Number of responses/respondents	Average burden/response (in hours)	Total burden (in hours)
Government researchers	48	1	1.89	90.8
University researchers	60	1	1.89	113.5
Private industry researchers	12	1	1.89	22.7
Total				227.0

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety Research: Availability of Cooperative Agreements; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is announcing the availability of research funds for fiscal year (FY) 1998 to conduct research to support the reduction of the incidence of foodborne illness, specifically to support: The development of sampling methods to enhance the detection, and more specifically the enumeration, of low levels of pathogens in foods; the development of intervention strategies for consumers to improve food safety in the home; and total genome sequence analyses of the pathogen *Escherichia coli* O157:H7, towards a molecular definition of microbial virulence and pathogenicity. Approximately $700,000 will be available in FY 1998. FDA anticipates making three to five awards at $100,000 to $200,000 (direct and indirect costs) per award per year. Support of these agreements may be up to 3 years. The number of agreements funded will depend on the quality of the applications received and the availability of Federal funds to support the project. After the first year, additional years of noncompetitive support are predicated upon performance and the availability of Federal FY funds. FDA is mandated by the President's Food Safety Initiative (FSI) to reduce the incidence of foodborne illness to the greatest extent feasible.

DATES: Submit applications by July 13, 1998. If the closing 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.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Robert L. Robins, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6170. (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: Robert L. Buchanan, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–500), 200 C St. SW., Washington DC 20204, 202–205–5053.

SUPPLEMENTARY INFORMATION: FDA will support the research studies covered by this notice under 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 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. 017–00100474–0) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, 202–512–1800.

I. Background

FDA is mandated by the President's Food Safety Initiative (FSI) to reduce the incidence of foodborne illness to the greatest extent feasible. 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 a year, primarily the very young and elderly, die as a result. Research in food safety seeks to reduce the incidence of foodborne illness by improving our ability to detect and enumerate pathogens in the food supply and to find new ways to control them. The President's FSI requires that 1998 funds be used to develop rapid cost effective tests for the presence in foods of pathogens and to develop technologies for preventing foodborne illness through the control of pathogens.

FDA has continually sponsored research to improve the detection of pathogens in foods. One area that may now be addressed is the problem of detecting sporadically-occuring low-level pathogens in foods. A caveat to employing existing detection regimens is the need to develop effective sampling strategies. Therefore, one objective of this funding initiative is the development of new approaches to sampling that will allow the use of existing detection regimens for screening larger sample volumes, thereby increasing the probability of detecting the presence of low levels of a pathogen. The ideal sampling method would: (1) Be nondestructive, (2) enhance the detection of multiple target microorganisms at or below current regulatory limits, (3) provide quantitative data of the level of the target pathogen to aid microbial risk assessment, and (4) be capable of being automated.

FDA has continually sponsored research in intervention strategies to mitigate the risk of foodborne illness. The initiative provides an opportunity to expand the range of research questions addressed by FDA in intervention strategies. The development of specific intervention strategies that may be used by consumers or food service providers is a priority need. A substantial number of disease outbreaks are associated with food consumption in the home or food service facilities, and in many of these incidences faulty food handling practices are identified as contributing factors. Some of these practices may be addressed by education. However, even with the strict adherence to recommended food handling practices, there is a risk of pathogenic microorganisms entering the home kitchen. Such hazards have traditionally been controlled by cooking, but this is not an option for many foods (e.g., lettuce, fresh fruit). New methods or technologies are needed that can empower the consumer and food service providers by providing them a means to actively reduce the incidence and prevalence of pathogens on foods that are not amenable to cooking. An effective intervention is one that can consistently reduce the levels of target pathogens (i.e, *Salmonella typhimurium*, *Listeria monocytogenes*, *E. coli* O157:H7, *Cyclospora cayetenensis*, *Cryptosporidium parvum*) by at least 1,000-fold under standardized test conditions. The funding initiative seeks to develop these new methods or technologies.

FDA has continually sponsored research for characterization of microbial virulence factors and the evolution of microbial survival and growth, especially as it impacts pathogenesis. The initiative provides an opportunity to expand the range of research questions addressed by FDA in the virulence and evolution of *E. coli* O157:H7. This pathogen is of special interest because of its virulence and resistance to traditional methods of food preservation. FDA needs to better understand the mechanisms of the pathogen's survival, growth, and evolution, with respect to the factors associated with its pathogenesis. An important tool for acquiring this information is the sequence of the genome of the pathogen. It is expected that sequence information of *E. coli* O157:H7 will provide unique insights into the evolution of the pathogen, particularly in comparison with nonpathogenic *E. coli* sequences. Further insights are anticipated with respect to identifying sequences of deoxyribonucleic acid from other organisms and deducing the mechanism of transfer based upon collateral sequences. Proposed research should initiate a pathway to the eventual development of rapid and sensitive methods for detection, identification, and enumeration of this important pathogen.

II. Research Goals and Objectives

The specific objectives of this program will be: (1) The development of sampling methods or strategies to facilitate existing detection methods towards detecting, and more importantly enumerating, low-level microbial pathogens in food; (2) the development of intervention strategies for use by consumers in the home and by food service providers that will reduce the incidence of food borne illness, particularly that associated with fresh or minimally processed produce; and (3) the expansion of knowledge of the genome of *E. coli* O157:H7, towards a molecular definition of pathogen emergence and resistance to traditional food processing/preservation practices.

Projects that fulfill any one of the following specific objectives will be considered for funding. Applications may address only one project objective; however, applicants may submit more than one application for any of the following project objectives:

A. Project Objective 1

Project objective 1 is intended to develop sampling and statistical methods that facilitate existing pathogen detection regimens to allow the detection, and more importantly enumeration, of low-levels of pathogens in or on foods, particularly fresh or minimally processed produce. Projects will be considered that seek to develop new ways of sampling large volumes of foods in a nondestructive or contaminating manner and provide quantitative estimates of the level of the pathogen to aid microbial risk assessment. Proposals may include any of a variety of potential isolation, recovery, and/or concentration systems, as long as they are suitable for use in food production, processing, or preparation facilities. An ideal sampling plan should also consider not only occurrence of pathogen(s), but also dispersion or distribution of the pathogen in the food. These pathogen enumeration and distribution data would aid reconstructing the estimated ingested dose that caused illness, lending support to development of dose-response models in microbial risk assessment. A plan for demonstrating the feasibility of the developed methodology in contaminated foods collected under ''field conditions'' should be included.

B. Project Objective 2

Project objective 2 is intended to develop intervention methods or technologies other than cooking that can be used by consumers in the home or by operators of food service facilities. Proposed approaches should provide consumers with new tools and methods that can enhance the microbiological safety of foods, particularly fresh or minimally processed produce, that is prepared in the home or food service facilities by decreasing the level of pathogens in or on the food. The proposed intervention strategy can be at any point between the consumer's, or food service proprietor's, purchase of a

food or food ingredient and its consumption. The proposed intervention strategy must be affordable and easy enough to perform so as to be adopted by consumers. The estimated performance characteristics of the proposed strategy, with respect to added safety, must be carefully detailed in the proposal and validated during the research if the grant is awarded. Validation will include testing with a variety of fresh vegetables and fruit with at least two of the five pathogens mentioned previously.

C. Project Objective 3

Project objective 3 is intended to provide genomic sequence data on *E. coli* O157:H7. Preference will be given to applicants demonstrating documented success of other genomic sequencing projects and well-developed sequencing plans for areas of the genome that have special relevance to food safety. Applicants must demonstrate that they can apply the most recent technology cost-effectively to the production of sequence data and show that they can adequately and efficiently accumulate, store, and disseminate those data for future interpretation and application. A commitment to and a plan for making the sequence data publicly available by deposition into an accessible sequence data base (GenBank and GSDB) within 3 months of data acquisition and annotation, must be included in the project description.

D. Protection of Human Research Subjects

Some activities carried out by a recipient under this announcement may be governed by Department of Health and Human Services (DHHS) regulations for the protection of human research subjects (45 CFR 46). These regulations require recipients to establish procedures for the protection of subjects involved in any research activities. Prior to funding and upon request of the Office for Protection from Research Risks (OPRR), prospective recipients must have on file with OPRR an assurance to comply with 45 CFR 46. This assurance to comply is called an assurance document. It includes the designated Institutional Review Board (IRB) for review and approval of procedures for carrying out any research activities occurring in conjunction with this award. If an applicable assurance document for the applicant is not already on file with OPRR, a formal request for the required assurance will be issued by OPRR at an appropriate point in the review process, prior to award, and examples of required materials will be supplied at that time. No applicant or performance site, without an approved and applicable assurance on file with OPRR, may spend funds on human subject activities or accrue subjects. No performance site, even with an OPRR-approved and applicable assurance, may proceed without approval by OPRR of an applicable assurance for the recipients. Applicants may wish to contacting OPRR by facsimile (301–402–0527) to obtain preliminary guidance on human subjects issues. When contacting OPRR, applicants should provide their institutional affiliation, geographic location, and all available request for application (RFA) citation information.

III. Reporting Requirements

A 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 Grants Management Officer within 90 days of the budget expiration date of the cooperative agreement. Failure to file the FSR (SF–269) on time may be grounds for suspension or termination of the agreement. Progress reports will be required quarterly within 30 days following each Federal fiscal quarter (January 31, April 30, July 30, and October 31), except that the fourth report will serve as the annual report and will be due 90 days after the budget expiration date. CFSAN program staff will advise the recipient of the suggested format for the Program Progress Report at the appropriate time. A final FSR (SF–269), 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 and the project advisory group. 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 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.

B. Eligibility

These cooperative agreements are available to any public or private nonprofit entity (including State and local units of government) and any for-profit entity. For-profit entities must exclude fees or profit from their request for support to receive grant 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

This agreement is planned for up to 3 years. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year, and/or (2) the availability of Federal fiscal year funds.

V. Delineation of Substantive Involvement

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will have a substantive involvement in the programmatic activities of all the projects funded under this RFA. Substantive involvement includes but is not limited to the following:

1. FDA will appoint project officers who will actively monitor the FDA supported program under each award.
2. FDA will establish a project advisory group which will provide guidance and direction to the project officer with regard to the scientific approaches and methodology that may be used by the investigator.
3. FDA scientists will collaborate with the recipient and have final approval on experimental protocols. This collaboration may include protocol design, data analysis, interpretation of findings, co-authorship of publications and the development and filing of patents.

VI. 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. 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 his designee.

B. Review Criteria

The funding priority categories are as follows:

Project Objective 1–first priority

Project Objective 2–second priority

Project Objective 3–third priority

All comments received on these funding priority categories will be taken into consideration and will receive a written response.

Applicants must clearly state in their applications which of the previously listed established funding priority categories is relevant to their proposed project. Applications will be grouped, reviewed, and ranked within each funding priority category. Funding priority will start with the highest ranked applications under each of the three objectives, then the second highest, etc., until available funds have been exhausted. All applications will be evaluated by program and grants management staff for responsiveness. Applications considered nonresponsive will be returned to the applicant, without being reviewed. 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 must be directed to the CFSAN program staff and all questions of an administrative or financial nature must be directed to the grants management staff. (See **FOR FURTHER INFORMATION CONTACT** caption at the beginning of this document.) Applications will be reviewed and scored on the following criteria:

1. Research should be proposed on microbiological sampling or intervention strategies that is within one of the three objectives listed in section II of this document;

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

3. Soundness of the rationale for the proposed study and appropriateness of the study design to address the objectives of the RFA;

4. Availability and adequacy of laboratory facilities and equipment;

5. Availability and adequacy of support services (e.g., biostatistical computer, data bases, etc.,); and

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

VII. Submission Requirements

The original and five copies of the completed Grant Application Form PHS 398 (Rev. 5/95) or the original and two copies of Form PHS 5161 (Rev. 7/92) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Robert L. Robins (address above). State and local governments may choose to use Form PHS 398 in lieu of the Form PHS 5161. The application closing date is July 13, 1998. 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 work day. No supplemental or addendum material will be accepted after the closing date. The outside of the mailing package and item 2 of the application face page should be labeled, ''Response to RFA FDA CFSAN–98–2, Project Objective 1 (2 or 3).''

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established closing date. Applications will be considered received on time if sent or mailed on or before the closing 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 (CSR), 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 forms can be found on NIH home page on the Internet (address: ''http://www.nih.gov.grants/funding/phs398/phs398.html''; the forms can be found at ''http://www.nih.gov/grants/funding/phs398/forms-toc.html''). However, as noted previously, applications are not to be mailed to NIH. 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. Applications must be submitted via mail delivery as stated previously. FDA is unable to receive applications via the Internet.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/95). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the closing dates and the mailing label address. Do not send applications to the CSR, NIH. Applications from State and local governments may be submitted on Form PHS 5161 (Rev. 7/92) or Form PHS 398 (Rev. 5/95).

The face page of the application should reflect the RFA number RFA–FDA–CFSAN–98–2, Project Objective 1 (2 or 3).

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 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.

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 information shall not be used or disclosed except for evaluation purposes.

Dated: May 18, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–13918 Filed 5–26–98; 8:45 am]

BILLING CODE 4160–01–F