TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Record | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 800.55(k) | 1 | 1 | 1 | 20 | 20 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Over the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. Historically, the Center for Devices and Radiological Health has had very few or no annual responses for this information collection and normally reports one response per year.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the three firms whose devices had been detained.

Dated: June 16, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–15995 Filed 6–24–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Food Safety and Security Research—Rapid Methods Development: Availability of Cooperative Agreements; Request for Applications; RFA–FDA–CFSAN–03–1

**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 approximately $3 million in research funds for fiscal year (FY) 2003. These funds will be used to support collaborative research efforts between CFSAN and scientists, and to complement and accelerate ongoing research in four project areas in order to reduce the incidence of foodborne illness and to ensure the integrity of the nation's food supply (including food additives and dietary supplements) and cosmetics. All awards will be subject to the availability of FY 2003 funds.

**DATES:** Submit applications by August 11, 2003.

**ADDRESSES:** Submit completed applications to: Rosemary Springer, Grants Management Specialist, Grants Management Staff (HFA–520), Division of Contracts and Procurement Management, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7182, e-mail: rspringe@oc.fda.gov. Hand-carried or commercially delivered applications should be sent to: Food and Drug Administration, 5630 Fishers Lane, rm. 2129, Rockville, MD 20857.

Application forms are available either from Rosemary Springer (see previous paragraph) or on the Internet at http://grants1.nih.gov/grants/funding/phs398/phs398.html. NOTE: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH). Applications mailed to CSR and not received by FDA in time for orderly processing will be returned to the applicant without consideration. Please note that FDA is unable to receive applications electronically.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the administrative and financial management aspects of this notice*: Rosemary Springer (see **ADDRESSES** section).

*Regarding the programmatic aspects of this notice*: John W. Newland, Research Coordinator, Office of Science (HFS–006), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1915, e-mail: john.newland@cfsan.fda.gov.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is committed to reducing the incidence of foodborne illness to the greatest extent feasible and to protecting the integrity of the nation's food supply. Research in food safety seeks to reduce the incidence of foodborne illness by improving our ability to detect, characterize, and quantitate foodborne pathogens, toxins and chemicals that could jeopardize the safety and security of the food supply, and to find new and improved ways to control these agents. Since 1998, CFSAN has supported multiyear cooperative agreements intended to help achieve the research goals of reducing the incidence of foodborne illness and ensuring the integrity of foods, including food additives and dietary supplements, and cosmetics. This extramural program supports novel collaborative research efforts between CFSAN and scientists, and leverages expertise not found within CFSAN to complement and accelerate ongoing research. Collaborations such as these provide information critical to food safety guidance and policymaking, help address the needs of CFSAN regulatory programs, stimulate fruitful interactions between FDA scientists and those within the greater research community, and benefit the American public.

In continuation of this effort to help enhance the capabilities of the agency, CFSAN is announcing the availability of research funds for FY 2003 to support research in the following four categories: (1) Development of rapid analytical screening methods for the detection of pathogens that are not usually associated with food and foodborne illness at a contamination level of 100 to 10,000 microbial pathogens/gram (g) of food without pregrowth or selective enrichment; (2) development of PCR-based methods for rapid confirmatory identification of pathogens that are not usually associated with food and foodborne illness; (3) development of rapid screening methods capable of detecting a broad range of nontraditional chemical and toxin adulterants; and (4) development of improved equipment, software, procedures, and/or methods for determining radionuclide contamination in foods.

Approximately $3 million will be available in FY 2003. FDA anticipates making awards of $100,000 to $600,000 (direct plus indirect costs) per award. The research efforts supported by these agreements may be up to 3 years in duration, however the total budget amount will not exceed a one-time amount of $600,000 (direct plus indirect costs) per award. The project and budget periods of these awards will be the same. Any application received that exceeds the amount stated previously will not be considered responsive and will be returned to the applicant without being reviewed. The number of agreements funded will depend on the availability of Federal funds to support the projects and on the quality of the applications received. There is no

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

and the Principal Investigator and/or a site visit with appropriate officials of the recipient organization. A record of these monitoring activities will be made in an official file specific for each cooperative agreement and may be available to the recipient of the cooperative agreement upon request.

**V. Delineation of Substantive Involvement**

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will have substantive involvement in the programmatic activities of all the projects funded under this notice and request for applications (RFA). Substantive involvement may include, but is not limited to, the following:

1. FDA will provide guidance and direction with regard to the scientific approach and methodology that may be used by the investigator;

2. FDA will participate with the recipient in determining and executing any: (1) Methodological approaches to be used, (2) procedures and techniques to be performed, (3) sampling plans proposed, (4) interpretation of results, and (5) microorganisms and commodities to be used; and

3. FDA will collaborate with the recipient and have final approval on the experimental protocols. This collaboration may include protocol design, data analysis, interpretation of findings, coauthorship of publications, and the development and filing of patents.

**VI. Review Procedure and Criteria**

An application must: (1) Be received by the specified due date; (2) be submitted in accordance with sections III.B ''Eligibility,'' VII. ''Submission Requirements,'' and VIII.A ''Submission Instructions'' of this document; (3) not exceed the recommended funding amount stated in section I of this document; (4) address only one of the four project categories identified in this notice and RFA; and (5) bear the original signatures of both the Principal Investigator and the institution's/organization's authorized official. If an application does not comply with these requirements it will be returned to the applicant without further consideration.

Applications meeting the previous requirements will be reviewed, evaluated, and scored for scientific and technical merit by a panel of experts in the subject field of the specific application.

Applications will be evaluated and scored on the following criteria:

1. Soundness of the scientific rationale for the proposed study, appropriateness of the study design, and the study's ability to address all of the objectives of the RFA and thereby protect the health of the American consumer;

2. Availability and adequacy of resources (laboratory facilities, equipment, and support services, e.g., biostatistics computational support, databases, etc.) to perform and achieve the expected results;

3. Qualifications, research experience and training of the principal investigator and other proposed staff to carry out their expected roles under the project; and

4. Whether the budget requested is realistic and reasonable in terms of the scope, aims and duration of the proposed project, including whether it is within budget guidelines, and whether all costs have been adequately justified and fully documented.

Funding recommendations are subject to review by a National Advisory Council for concurrence with the recommendations made. Final funding decisions will be made by the Commissioner of Food and Drugs or his designee.

Applicants must clearly state in their application the project category for which they are applying. There is no assurance that awards will be made in each of the four project categories. If a project category is funded, funding will start with the highest ranked application within that project category, and any additional awards within that project category will be made based on the next highest ranked 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 of this document.)

**VII. Submission Requirements**

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or the original and two copies of PHS 5161–1 (Rev. 7/00) for State and local governments (no appendices) should be delivered to Rosemary Springer (see **ADDRESSES**). State and local governments may choose to use the PHS 398 application form in lieu of PHS 5161–1. 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–03–1[ ]'' (insert Project # 1, 2, 3, or 4 within the brackets).

**VIII. 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, and 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 previously. 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 the NIH on its applications. NOTE: Applicants must limit the Research Plan sections of their applications to 10 pages and that no appendices should be included with the applications.

*B. Format for Application*

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or PHS 5161–1 (Rev. 7/00) for State and local government applicants. 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 RFA number, RFA–FDA–CFSAN–03–[ ], (insert Project # 1, 2, 3, or 4 within the brackets).

Data included in the application, if identified by the applicant as trade secret or confidential commercial information, will be given treatment as such to the extent permitted by 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.

Dated: June 19, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–15964 Filed 6–24–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003N–0281]**

### Severe Acute Respiratory Syndrome Diagnostics: Scientific and Regulatory Challenges Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop to discuss methods for evaluating new diagnostic tests for severe acute respiratory syndrome (SARS). The purpose of this workshop is to serve as a public forum for interested stakeholders and FDA to consider resources and methods to evaluate SARS diagnostic tests. In addition, the workshop serves as an opportunity to provide mechanisms for public-private partnerships and sharing of both information and resources to facilitate evaluation and safe use of new diagnostic tests.

*Date and Time*: The public workshop will be held on July 14, 2003, from 8 a.m. to 5 p.m.

**ADDRESSES**: The public workshop will be held at the DoubleTree Rockville Hotel and Executive Meeting Center (*http://www.doubletreerockville.com*), 1750 Rockville Pike, Rockville, MD 20852, 301–468–1100, FAX: 301–468–0163. The hotel may be reached by Metro using the Twinbrook station on the red line. Submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: *FDADockets@oc.fda.gov*. Online registration, additional information about the meeting, and directions to the facility are available on the Internet at: *http://www.fda.gov/cdrh/meetings/071403.html*.

*Contact Person*: Cynthia Benson, Center for Devices and Radiological Health (HFZ–3), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–7989, e-mail: *cmh@cdrh.fda.gov*.

*Agenda*: At the workshop, FDA will receive questions and comments from stakeholders likely to be affected by FDA policies or procedures regarding SARS diagnostic tests. Stakeholders include, but are not limited to, medical device product manufacturers, members of the academic and clinical communities, and consumer and patient advocacy groups.

*Registration*: Preregistration is required by July 7, 2003, and will be accepted on a first-come, first-served basis; however, notwithstanding attendance at the workshop, interested persons are encouraged to provide comments (see the *Request for Comments* section of this document). Please register online at *http://www.fda.gov/cdrh/meetings/071403.html*. Persons without Internet access may call 1–888–203–6161 to register. To accommodate overnight attendees, a limited number of reserved rooms are available by calling the DoubleTree Rockville Hotel and Conference Center (see the **ADDRESSES** section of this document). Please register with the hotel by June 30, 2003. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the workshop. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/071403.html*. Persons without Internet access may call 1–888–203–6161 to register. Please register by July 7, 2003. FDA will provide audio conference participants the opportunity for comments and questions by fax (fax number to be provided at the workshop).

If you need special accommodations due to a disability, please contact Shirley Meeks at 301–594–1283 at least 7 days in advance.

*Request for Comments*: Regardless of attendance at the workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see the *Addresses* section of this document). Submit two paper copies of any mailed comments. Individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. The comments that FDA receives will be made available at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

*Transcripts*: Following the workshop, transcripts will be available for review at the Division of Dockets Management (see the **ADDRESSES** section of this document).

**SUPPLEMENTARY INFORMATION:** The objectives of the workshop are to discuss methods for evaluating new SARS assays for clinical and public health use and to develop information on availability and access to control materials, reagents, and specimens needed for development and qualification of SARS diagnostic assays. FDA hopes to address unique issues related to the evaluation of nucleic acid amplification, direct antigen, and serologic assays. FDA also wishes to promote partnerships among government, industry, health care providers, and the clinical laboratory community that would facilitate the development of new SARS diagnostic assays through sharing of information and resources.

Dated: June 20, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–16232 Filed 6–23–03; 3:07 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will