[FR Doc. 02–9197 Filed 4–12–02; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0276]

Agency Information Collection Activities; Announcement of OMB Approval; Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods with Vinclozolin Residues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods with Vinclozolin Residues'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 23, 2001 (66 FR 53614), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0484. The approval expires on March 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: April 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–9097 Filed 4–12–02; 8:45 am]
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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), in this request for applications (RFA), is announcing the availability of approximately $750,000 in research funds for fiscal year (FY) 2002. These funds will be used to support collaborative research efforts between the Center for Food Safety and Applied Nutrition (CFSAN) and scientists and to complement and accelerate ongoing research in five project areas in order to reduce the incidence of foodborne illness and to protect the nations's food supply, food additives, and dietary supplements.

DATES: Submit applications by May 30, 2002.

ADDRESSES: Submit completed applications to Maura Stephanos, Grants Management Specialist, Grants Management Staff (HFA–520), Division of Contracts and Procurement Management, Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183, FAX 301–827–7106, e-mail: mstepha1@oc.fda.gov. Application forms are available either from Maura Stephanos (address above) or on the Internet at http://grants.nih.gov/grants/funding/phs398/phs398.html. NOTE: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH).

FOR FURTHER INFORMATION CONTACT: Regarding the administrative and financial management aspects of this notice: Maura Stephanos (address above).

Regarding the programmatic aspects of this notice: John W. Newland, Microbial Research Coordinator, Office of Science (HFS–06), 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 and quantitate foodborne pathogens, toxins and chemicals that could jeopardize the security of the food supply, and to find new and improved ways to control these agents. CFSAN supports multiyear cooperative agreements intended to help achieve these research goals of reducing the incidence of foodborne illness and ensuring the integrity of foods, food additives, and dietary supplements. 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, and stimulate fruitful interactions between FDA scientists and those within the greater research community.

In continuation of this effort, CFSAN will provide FY 2002 funds to be used for research to help enhance the following capabilities of the agency: The ability to detect and control the presence of human pathogens, food allergens, toxins, and other bioactive compounds that may be present in FDA-regulated products; and the development of a framework by which the possible risk posed by potential high threat agents that might be used to adulterate particular foods, food additives, and dietary supplements can be ranked and systematically evaluated.

FDA is announcing the availability of research funds for FY 2002 to support research in the following five project categories: (1) Development and implementation of a risk-ranking framework to evaluate potential high threat microbiological agents, toxins, and chemicals in food; (2) practical application of laboratory based biosensor detection technology to detect and analyze microbiological agents, food allergens, toxins, and other bioactive compounds in foods, food additives, and dietary supplements; (3) multi-residue capillary gas chromatographic/mass spectrometric (GC/MS) technique for the detection of chemicals that may be present as contaminants in foods, food additives, and dietary supplements; (4) evaluation of the efficacy of multiple heat treatments used during the production of dairy products relative to the inactivation of bacterial spores; and (5) development of a bioinformatic approach, using predictive algorithms and protein sequence databases (structural proteomics), to identify the potential allergenicity of food proteins. Approximately $750,000 will be available in FY 2002. Of this amount,

$500,000 will be available for projects 1 through 4 detailed in section II ''Research Goals and Objectives'' of this document, and $250,000 will be available for project 5 also detailed in section II ''Research Goals and Objectives'' of this document. For projects 1 through 4, FDA anticipates making up to three awards of $100,000 to $200,000 (direct plus indirect costs) per award per year. Support of these agreements may be up to 3 years in duration with the total budget amount not to exceed $200,000 (direct plus indirect costs) per year or a total of $600,000 for a 3-year award.

For project 5, FDA anticipates making one award up to $250,000 (direct plus indirect costs) per year. Support for this project may be up to 3 years in duration with a total budget amount not to exceed $250,000 (direct plus indirect costs) per year or a total of $750,000 for a 3-year award. Any application received that exceeds the amounts stated above 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 five project categories. After the first year, additional years of noncompetitive support are predicated upon performance and the availability of Federal funds.

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 hard copy of the ''Healthy People 2010'' objectives, vols. I and II, conference edition (B0074) for $22 per set, by writing to the Office of Disease Prevention and Health Promotion (ODPHP) Communication Support Center (Center), P.O. Box 37366, Washington, DC 20013–7366. Each of the 28 chapters of ''Healthy People 2010'' is priced at $2 per copy. Telephone orders can be placed at the Center by calling 301–468–5690. The Center also sells the complete conference edition in CD–ROM format (B0071) for $5. This publication is also available on the Internet at http://health.gov/healthypeople. Internet viewers should select ''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. It should be emphasized that in all of the following projects, there is a particular desire to promote the development of improved techniques for either the detection, control, or risk ranking of microbiological agents, toxins, allergens and chemicals in food. Such agents include but are not limited to, *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, *Clostridium botulinum*, *Salmonella Enterica*, pathogenic *Escherichia coli*, acetylcholinesterase inhibitors, botulinum toxins, abrin, tricothecenes, rodenticides, amanitine, and other natural toxins. None of the five projects should involve human research subjects that are not exempt from the Department of Health and Human Services (DHHS) regulations (45 CFR part 46) for the protection of human research subjects. The projects and their objectives are as follows.

A. Project 1: Development and Implementation of a Risk-Ranking Framework to Evaluate Potential High Threat Microbiological Agents, Toxins, and Chemicals in Food

A risk-ranking framework is needed to facilitate the evaluation and ranking of potential high threat microbiological agents, toxins, and chemicals that can be used to contaminate food. The framework will include a model for quantitatively or semiquantitatively comparing and determining the potential threats of these agents and the ability to evaluate intervention or control points for food industry, manufacturers/processing, warehouses, transport, retail, etc., to protect the food supply. Implementation of the framework would include using existing and newly developed lists of agents and systematically ranking threats. Criteria used in the framework for ranking purposes could include but would not be limited to, compatibility with food as a vehicle, toxicity (or needed dose), accessibility, and likelihood of effect (illness).

B. Project 2: Practical Application of Laboratory Based Biosensor Detection Technology to Detect and Analyze Microbiological Agents, Food Allergens, Toxins, and Other Bioactive Compounds in Foods, Food Additives, and Dietary Supplements

The objective of this project is to obtain customer ready technology that combines immunoassay capture techniques with appropriate detector technology, such as an optical transducer or a mass spectrometer for use in the rapid detection and identification of microbiological agents and toxins in FDA-regulated products (i.e., food). This will provide a new detection methodology critical to FDA's food surveillance programs, which are designed to keep hazardous substances out of the food supply. Research must specifically focus on the detection of a variety of microbial agents, toxins, and other bioactive compounds in a number of different food matrices. The analytical method resulting from this research will provide an accurate, fast, and cost-effective means of screening food products.

C. Project 3: Multi-Residue Capillary Gas Chromatographic/Mass Spectrometric (GC/MS) Technique for the Detection of Chemicals That May Be Present as Contaminants in Foods, Food Additives and Dietary Supplements

The objective of this project is the development of an analytical technique, based on GC/MS, which can be used for the identification of a number of chemical toxins in foods. The awardee will produce a single validated procedure that can be used to screen various foods, food additives, and dietary supplements for a number of chemical toxins. The method will be capable of identifying a number of classes of chemical agents including but not limited to pesticides, rodenticides, and mycotoxins in these FDA-regulated products (i.e., food). This research will provide a new analytical methodology critical to FDA's food surveillance programs, which are designed to identify and avoid possible hazardous substances in the food supply.

D. Project 4: Evaluation of the Efficacy of Multiple Heat Treatments Used During the Production of Dairy Products Relative to the Inactivation of Bacterial Spores

Multiple heat treatments are used during the manufacture of a variety of dairy products. For example, in the production of most cheeses there are two to four heating steps (milk pasteurization, cooking and primary

fermentation, secondary fermentation, and extruding). Pasteurization may in some instances heat-shock spores into germination. A study is sought to determine whether the effect of multiple heat treatments in the production of these products is sufficient to destroy vegetative cells and/or spores and possible toxins that might arise from the presence of spores of *C. botulinum* and *B. anthracis*.

E. Project 5: Development of Bioinformatic Approachs, Using Predictive Algorithms and Protein Sequence Databases (Structural Proteomics), to Identify the Potential Allergenicity of Food Proteins

The objective of this project is to identify Immunoglobulin E (IgE)-binding epitopes or other structural characteristics of known food allergens to establish structure-prediction algorithms, which will eventually allow scientists to predict structure and function from protein sequence. For this project, the prediction of structure and function from sequence is focused on establishing the potential allergenicity of food proteins or to identify previously unknown food allergens. An evaluation of the feasibility of bioinformatic approaches to characterize or rank the potential allergenicity of food proteins could be modeled after predictive capabilities of currently available methods or databases for identification of IgG- or Major Histocompatability Complex (MHC)- binding epitopes or pharmaceutical target binding sites. This research should lead to the development of rapid methods for evaluation of potential food allergens (e.g, in bioengineered foods and ingredients) and be directed toward validation of these methods using biological systems, such as enzyme immunoassay or other quantitative methods.

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. NIH's 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

The length of support will be 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 (2) availability of Federal FY funds.

IV. Reporting Requirements

Annual Financial Status Reports (FSR) (SF–269) are required. An original FSR and two copies shall be submitted to FDA's Grants Management Officer (address same as given above for Grants Management Specialist) within 90 days of the budget expiration date of the cooperative agreement. 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 except that the fourth quarterly report which will serve as the annual report and will be due 90 days after the budget expiration date. For continuing agreements, an annual Program Progress Report is also required. Submission of the noncompeting continuation application (PHS 2590) will be considered as the annual Program Progress Report. 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 Washington, DC. Travel costs for this requirement should be specifically requested by the applicant as part of their 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 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. A record of these monitoring activities will be duly 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 a substantive involvement in the programmatic activities of all the projects funded under this 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: (a) Methodological approaches to be used, (b) procedures and techniques to be performed, (c) sampling plans proposed, (d) interpretation of results, and (e) microorganisms and commodities to be used.

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

A. Review Method

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. To be responsive, an application must: (1) Be received by the specified due date; (2) be submitted in accordance with section III.B ''Eligibility,'' section VII ''Submission Requirements,'' and section VIII.A ''Submission Instructions'' all of this document; (3) not exceed the recommended funding amount stated in section I of this document; (4) address only one of the five project categories identified in this RFA; (5) address specific requirements of individual projects as stated in section II ''Research Goals and Objectives'' of this document; and (6) bear the original signatures of both the Principal Investigator and the Institution's/Organization's Authorized

Official. 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 designee.

B. Review Criteria

Applicants must clearly state in their application for which of the requested projects they are applying. All applications will be evaluated by program and grants management staff for responsiveness. Applications will be reviewed and ranked within each project category. There is no assurance that awards will be made in each of the five 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 (See the **FOR FURTHER INFORMATION CONTACT** section of this document for addresses.), and all questions of an administrative or financial nature should be directed to Maura Stephanos of the Grants Management Staff (address above).

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., bio-statistics 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.

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, with copies of the appendices for each of the copies, should be delivered to Maura 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 May 30, 2002. 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–02–1, (insert Project #1, 2, 3, 4, or 5).''

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal business hours, from 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 (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 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 Rev. 5/01) 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–02–1, (insert Project #1, 2, 3, 4, or 5).

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. The requirements requested on Form PHS 5161–1 were approved and assigned OMB control number 0348–0043.

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 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: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–9098 Filed 4–12–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0115]

Risk Management of Prescription Drugs; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is announcing a public hearing on the agency's approach to risk management of prescription drugs. In May 1999, FDA published ''Managing the Risks From Medical Product Use,'' which laid a framework for the agency's efforts to reduce the risks involved with medical product use. The public hearing announced in this notice is part of the agency's ongoing efforts to improve CDER's risk communication and to develop new and effective risk management tools. The purpose of the