AR–21 Small, Minority, Women-Owned Businesses
AR–22 Research Integrity

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—*http://www.cdc.gov* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

For business management assistance, contact: Van A. King, Grants Management Specialist ,Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: (770)488–2751, E-mail address: *Vking@cdc.gov.*

For program technical assistance, contact: Leroy Frazier, Jr., MSPH, CHES, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Hwy, NE, MS K60, Atlanta, GA 30341, Telephone number: (770)488–1507, E-mail address: *Lfrazier1@cdc.gov.*

Dated: June 27, 2002.

Sandra R. Manning,

CGFM Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 02–16814 Filed 7–3–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement To Support the Joint Institute for Food Safety and Applied Nutrition; Notice of Intent To Renew a Cooperative Agreement; RFA–FDA–CFSAN–02–04

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single source application for the award of a cooperative agreement in fiscal year (FY) 2002 to the University of Maryland, College Park (UMCP) to support the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), which is located on the University of Maryland campus in College Park, MD. An estimated amount of support in FY 2002 will be up to $3 million per year (direct and indirect costs), with an additional 4 years of support. Competition is limited to UMCP because of the unique partnership between FDA and UMCP. The cooperative agreement will continue to allow for a more efficient use of research, education, and outreach resources which enhances overall public health by expanding and improving food safety and nutrition programs as well as other program areas that impact on public health policy.

DATES: Submit the application by August 19, 2002. If this date falls on a weekend, it will be extended to Monday; if this date falls on a holiday, it will be extended to the following workday.

ADDRESSES: The completed application should be submitted to Peggy Jones, Grants Management Officer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. If the application is either hand carried or commercially delivered, it should be addressed to Peggy Jones, 5630 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7160, FAX 301–827–7101, e-mail address: pjones1@oc.fda.gov.

The application forms are available either from Peggy Jones (see **ADDRESSES**) or by the Internet at http://grants.nih.gov/grants/funding/phs398/phs398.html. NOTE: Do not send the application 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: Peggy Jones (see **ADDRESSES**).

Regarding the programmatic aspects: Christine L. Hileman, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–7153; e-mail: Chileman@CFSAN.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing its intention to accept and consider a single source application from UMCP for a cooperative agreement to support JIFSAN. FDA's authority to enter into grants and cooperative agreements is set out in 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. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public. This application is not subject to review under Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100).

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.

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, volumes I and II, conference edition (B0074) for $22 per set, by writing to the Office of Disease Prevention and Health Promotion 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 to the Center on 301–468–5690. The Center also sells the complete conference edition in CD-ROM format (B0071) for $5. This publication is available as well on the Internet at http://health.gov/healthypeople. Internet viewers should proceed to ''Publications.''

I. Background

Through a formal Memorandum of Understanding (MOU) between FDA and UMCP, JIFSAN was established in April 1996. JIFSAN creates a partnership that allows for more efficient use of research, education, and outreach resources, thereby enhancing overall public health by expanding and improving food safety and nutrition programs as well as in other program areas that impact on public health policy. The primary focus of JIFSAN is food safety and nutrition, specifically as related to risk analysis, applied microbiology, natural toxins, chemical contaminants, animal health sciences, biotechnology and food composition and nutrition. JIFSAN also encompasses other program areas such as cosmetics, dietary supplements, and food labeling.

In the **Federal Register** of May 22, 1997 (62 FR 28049), FDA published a request for a single source application for a cooperative agreement to support JIFSAN. The application was reviewed and approved by an ad hoc panel of experts. The panel's approval recommendation was then approved by the National Advisory Environmental Health Sciences Council in September 1997. FDA awarded the cooperative agreement to UMCP on September 30, 1997.

In the **Federal Register** of July 26, 1999 (64 FR 40380), FDA published a

notice of its intention to noncompetitively supplement the cooperative agreement with UMCP. FDA awarded the noncompetitive supplement to the cooperative agreement with UMCP on September 29, 1999.

JIFSAN is a jointly administered, multidisciplinary research, education, and outreach program. Under the cooperative agreement, UMCP has established and staffed the JIFSAN at the UMCP campus. UMCP has established core facilities that enable FDA and the University to share resources, such as major laboratory instrumentation, and has initiated a mechanism to permit access to the university's library facilities for appropriate FDA employees. Programs initiated by JIFSAN have demonstrated that the benefits from this partnership are substantial. The unique administrative structure of JIFSAN allows it to most effectively use resources to plan, organize, and run multidisciplinary, multiinstitutional programs in research, education, and outreach. The structure and policies of a major land-grant university offer the flexibility needed to enable JIFSAN to create and operate strategic alliances involving multiple partners and multiple funding sources. JIFSAN provides a neutral environment in which experts from industry, consumer and trade groups, international organizations, government agencies, and academia pool their resources and ideas to provide the scientific bases for the development of sound public health policy.

II. Goals and Objectives

A. Concept

FDA believes that the cooperative research with UMCP through JIFSAN will further research related to food safety, will help to ensure the security of the American food supply, and will provide opportunities to leverage additional resources so that important national and international problems in food, nutrition, animal health science activities, cosmetics, dietary supplements, biotechnology, and food labeling can be addressed in a timely manner. FDA also believes that cooperative research through JIFSAN will promote the efficient use of the complementary resources (e.g., major instrumentation, space, information, and computer technologies) of both parties. All research will be related to FDA program requirements that ensure the safety of food.

B. Project Emphasis

The purpose of this cooperative agreement will be to continue to:

1. Develop a critical mass of scientific expertise to address ongoing and increasingly complex key public health issues, to provide early warning of emerging problems, to provide support during emergencies and crisis situations, and to provide scientific expertise in close proximity to FDA's administrative office to expedite regulatory policy and decisions. (All official regulatory activities, however, will be performed by FDA employees only);
2. Provide a collaborative environment and expertise for more efficient use of current resources devoted to risk analysis and biotechnology research and related activities;
3. Develop more effective methods for communicating public health policy and risk associated with both microbial and chemical hazards to the general public by going beyond the study of the science to the study of how that science is heard and understood;
4. Share resources to enhance the research infrastructure and provide for effective use of increasingly sophisticated scientific equipment with high acquisition, installation, and maintenance costs and the corresponding expertise of both parties; and
5. Establish mechanisms for exchange of technical information and scientific concepts between FDA, other Federal and State agencies, industry, academia, consumer and trade groups, and international organizations.

C. Summary of Future Objectives

The MOU between FDA and UMCP continues to provide the essential foundation for a vigorous, high quality scientific research program to support sound regulatory policy and performance. FDA faces an increasing number of critical and complex food safety issues. Having a nearby source of complementary and specialized scientific expertise and facilities, enhances FDA's ability to respond rapidly to regulatory challenges and to expedite regulatory policy and decisions. FDA believes that JIFSAN is a sound investment to ensure the public health of American consumers. It provides an opportunity for extensive cooperation with University scientists, and it will significantly stimulate collaborative efforts between Government, academia, industry, and consumers to improve and ensure a safe food supply.

The American people will benefit from this type of collaboration because it will ensure that FDA is positioned to respond rapidly in crisis situations to protect, promote, and enhance the health of the public.

III. Mechanism of Support

A. Award Instrument

Support of this program, if awarded, will be in the form of a cooperative agreement. In FY 2002, FDA anticipates providing up to $3 million (direct and indirect costs) for this award. It is anticipated that funding will remain at this level in the subsequent noncompetitive years unless appropriations change. The award 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, 45 CFR part 74, and the PHS grants policy statement.

B. Length of Support

The length of support will be 1 year, with the possibility of an additional 4 years of noncompetitive support. Continuation, beyond the first year, will be based upon satisfactory performance during the preceding year and the availability of Federal fiscal year appropriations.

IV. Reasons for Single Source Selection

UMCP is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. UMCP is in close proximity to the congressionally directed location of FDA's Center for Food Safety and Applied Nutrition's (CFSAN's) and Center for Veterinary Medicine's (CVM's) offices and laboratories in Prince Georges's County, MD. UMCP has vast resources, which complement and greatly expand FDA's research, scientific, and outreach resources. UMCP is the Washington region's most comprehensive research institution, with numerous academic programs relevant to FDA's mission and the resources to support CFSAN's areas of interest, including: Microbiology, chemistry, food science, animal health sciences, biotechnology, agriculture, public policy, risk assessment, computational science, economics, and survey methodology. UMCP serves as the primary center for graduate study and research and provides undergraduate instruction across a broad spectrum of academic disciplines. The University extends its vast intellectual resources to the community through innovative projects designed to serve individuals, governments, and the private sector throughout the State of

Maryland, the nation, and the international community. In 1988 the General Assembly of Maryland designated UMCP as the flagship institution for the University of Maryland System, which consists of 11 campuses across the State and offers programs at some 200 sites worldwide.

The University has developed core facilities to provide effective use of state-of-the-art scientific instrumentation with high acquisition, installation, and maintenance costs to conduct research at the forefront of science. An electron microscopy facility jointly supported by FDA and the University opened in 2000. CFSAN has moved its nuclear magnetic resonance (NMR) instrumentation and personnel to the University's NMR facility in the Chemistry building. These instrumentation centers complement CFSAN's resources and expertise.

The University has developed a food safety risk analysis clearinghouse with oversight from the interagency risk assessment consortium (RAC) established under the auspices of the former administration's Food Safety Initiative. The intent of the clearinghouse is to provide a centralized information source in areas of risk analysis related to food safety with initial emphasis on microbial pathogens and their toxins. The unique feature of this clearinghouse model lies in the examinations and documentation of state-of-the-art methods, data sources, and current results of on-going risk assessments so that a much more complete and up-to-date picture of risk assessment is assembled.

Acknowledging the importance of an interdisciplinary approach to knowledge, the University maintains organized research units outside the usual department structures (i.e., Department of Chemistry and Biochemistry and Department of Molecular, Cell and Microbial Biology, etc.). Through the collaborative projects, FDA has access to additional University resources that include: (1) The Center for Research in Public Communication, where cooperative projects related to risk communication studies could be developed; (2) the Survey Research Center and the Institute for Philosophy and Public Policy, which will promote more efficient development and dissemination of public policy; (3) the University of Maryland's Biotechnology Institute, including its Center for Agricultural Biotechnology, which will facilitate the development of a biotechnology program focused on food safety and nutrition; and (4) the Maryland Fire and Rescue Institute, which will facilitate the maintenance of emergency response readiness credentials of the FDA Safety Staff who are responsible for maintaining and ensuring safety and regulatory compliance at FDA facilities where collaborative research is conducted.

Collaboration between the public and the private sectors has proven to be an efficient means for both FDA and the University to remain current with scientific and technical advances related to food safety and applied nutrition. These collaborative programs produce knowledge and expertise that can be used by all segments of the food safety and nutrition community, as well as by public health organizations, other Federal agencies, and academic institutions in the performance of their roles. The partnership between FDA and UMCP provides both the technical and educational expertise for effective creation of technology transfer mechanisms that facilitate the movement of new technology and provides fundamental food safety and nutrition information to the public and private sector.

V. Reporting Requirements

Program progress reports and financial status reports will be required annually, based on date of award. These reports will be due within 90 days after the end of the budget period. A final program progress report and financial status report will be due 90 days after expiration of the project period of the cooperative agreement.

VI. Delineation of Substantive Involvement

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the projects funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

1. FDA will have prior approval of the appointment of all key administrative and scientific personnel proposed by the grantee.

2. FDA will be directly involved in the guidance and development of the program and of the personnel management structure for the program.

3. FDA scientists will participate, with the grantee, in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings, and, where appropriate, coauthorship of publications.

VII. Review Procedures

First, the grants management and program staff will review the application submitted in response to this request for application (RFA) for responsiveness. To be responsive, an application must: (1) Be received by the specified due date, (2) be submitted in accordance with sections VIII. ''Submission Requirements'' and IX.A. ''Submission Instructions'' of this document, (3) not exceed the recommended funding amount stated in the **SUMMARY** of this document, (4) address the specific program goals and objectives as detailed in section II.B. ''Project Emphasis'', and (5) bear the original signatures of both the principal investigator and the University's authorized official. Staff will consider the application nonresponsive if it does not contain the information set forth in this section. If the application is found to be nonresponsive, the staff will return the application to the applicant without further consideration. The staff will also consider an application nonresponsive for any of the following reasons: (1) The applicant organization is ineligible, (2) it is received after the specified receipt date, (3) it is incomplete, (4) it is illegible, (5) it is not responsive to the RFA, or (6) the material presented is insufficient to permit an adequate review.

Next, if the application is responsive, it will undergo a dual peer review. A responsive application will be reviewed first for scientific and technical merit by an ad hoc panel of experts in areas associated with food safety, nutrition, animal health sciences, biotechnology, and risk analysis. The application will then be presented to the National Advisory Environmental Health Sciences Council for their concurrence with the ad hoc panel's recommendation.

VIII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (rev. 4/98 or Rev. 5/01) with copies of the appendices for each of the copies, must be delivered to Peggy Jones (see **ADDRESSES**). No supplemental or addendum material will be accepted after the receipt date.

IX. Method of Application

A. Submission Instruction

An application from UMCP 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. The application 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 dated receipt from a commercial carrier, unless it arrives too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. An application not received on time will not be considered for review and will be returned to the applicant. (The applicant 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 the application to the CSR, NIH. The application must be submitted via mail or hand delivered as stated above. FDA is unable to receive the application electronically. The applicant is advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH for 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). All ''General Instructions'' and ''Specific Instructions'' in the application kit must be followed with the exception of the receipt dates and the mailing label address.

The face page of the application must reflect the request for application number, RFA-FDA CFSAN–02–3.

Data and information 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 0925–001.

Dated: June 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16817 Filed 7–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0253]

Withdrawal of 53 Guidances on Individual Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of 53 individual product labeling guidances. The guidances are being withdrawn because they are outdated and of little use to the generic drug industry. The agency has developed other guidance and resources to assist industry in obtaining up-to-date labeling for reference listed drugs.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written requests for the guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling'' to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Rita Hassall, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION: FDA is announcing the withdrawal of 53 individual product labeling guidances. These labeling guidances, currently available on the Center for Drug Evaluation and Research (CDER) guidance list, were intended to provide sponsors of abbreviated new drug applications (ANDAs) with product specific templates for package insert labeling that would be accepted by the Office of Generic Drugs (OGD). Package insert labeling for innovator products changes frequently, and it is difficult to keep the guidances updated. The guidances are being withdrawn because they are outdated and of limited use to the generic drug industry.

The withdrawal of these 53 product specific labeling guidances is part of a long-term effort in OGD to review guidance documents on the development of generic drug products with the goal of identifying documents that need to be revised, reformatted, or withdrawn because they are no longer current (64 FR 36886, July 8, 1999).

The following guidances are withdrawn:

Guidance	Date of Issuance
Acetaminophen, Aspirin and Codeine Phosphate Tablets and Acetaminophen, Aspirin and Codeine Phosphate Capsules	Revised December 1993
Acetaminophen and Codeine Phosphate Oral Solution and Oral Suspension	Revised December 1993
Alprazolam Tablets	Revised August 1996
Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP	September 1997
Amlodipine Besylate Tablets	September 1997
Astemizole Tablets	September 1997
Atenolol Tablets	August 1997
Butalbital, Acetaminophen and Caffeine Tablets USP or Butalbital, Acetaminophen and Caffeine Capsules USP	September 1997
Butalbital, Acetaminophen, Caffeine and Hydrocodone Bitartrate Tablets	September 1997
Butorphanol Tartrate Injection USP	Revised October 1992
Captopril and Hydrochlorothiazide Tablets USP	April 1995
Captopril Tablets	February 1995
Carbidopa and Levodopa Tablets USP	Revised February 1992
Cimetidine Hydrochloride Injection	September 1995
Cimetidine Tablets USP	Revised September 1995
Cisapride Oral Suspension	September 1997
Cisapride Tablets	September 1997
Clindamycin Phosphate Injection, USP	Revised September 1998
Diclofenac Sodium Delayed-Release Tablets	Revised February 1995
Diltiazem Hydrochloride Extended-Release Capsules	Revised September 1995