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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 Supplement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to noncompetitively supplement the cooperative agreement with the University of Maryland, College Park (UMCP) for up to an estimated \$2 million per annum. These funds will provide additional support to the UMCP's Joint Institute for Food Safety and Applied Nutrition (JIFSAN) for the purpose of addressing emerging health issues and crises that are related to food safety and applied nutrition and animal health sciences, and expanding the current scope to include other agency programs such as cosmetics.

DATES: Submit the application by (*insert date 30 days after date of publication in the Federal Register*). 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: An application is available from and should be submitted to: Maura C. Stephanos, Office of Regulatory Affairs Support and Assistance Management Branch (HFA-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7183. If the application is hand carried or commercially delivered, it should be addressed to Maura C. Stephanos, 5630 Fishers Lane, rm. 2129, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Maura C. Stephanos (address above).

Regarding the programmatic aspects: Elizabeth M. Calvey, Center for Food Safety and Applied Nutrition (HFS-6), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4716.

SUPPLEMENTARY INFORMATION: This project is authorized under section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). This activity is generally described in the Catalog of Federal Domestic Assistance at No. 93.103. The application will not be subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Program (45 CFR part 100).

I. Restricted Eligibility

In the **Federal Register** of May 22, 1997 (62 FR 28049), FDA announced that a single source application for a cooperative agreement to support the JIFSAN at the UMCP would be accepted. Supplemental funding referenced herein will provide for the implementation and enhancement of activities associated with the JIFSAN projects described and authorized under the original award (FD-U-001418-01) dated September 29, 1997.

II. Availability of Funds

FDA will provide supplemental funding up to an estimated \$2 million per annum to the cooperative agreement, which is at a level greater than the 25 percent of the original award currently provided under agency policy. Supplemental funding will provide support of the JIFSAN programs primarily through available Food Safety Initiative funds and funds from other government agencies.

The original cooperative agreement was approved for 5 years of funding and currently has 3 years of noncompetitive support remaining, which is contingent upon the availability of fiscal year appropriations and successful performance. FDA anticipates that supplemental funding of the cooperative agreement will commence on or before September 30, 1999.

III. Background

JIFSAN was established between FDA and the UMCP in April 1996, through a formal Memorandum of Understanding (MOU), to create a partnership that allows for more efficient use of research resources, thereby enhancing overall public health by expanding and improving food safety and nutrition research as well as research in other program areas that impact on public health policy. As the role of FDA research scientists in regulatory activities increases (e.g., petition review, rulemaking, enforcement compliance standards, hazard analysis critical control point performance standards), it is vital that these same scientists have ready access to very specialized research facilities and expertise that are in close proximity to FDA's administrative offices. The unique needs for research in support of regulatory programs has been one of the key reasons for maintaining a strong FDA research program. JIFSAN is a jointly administered, multi-disciplinary research and outreach program. JIFSAN was established as part of FDA's consolidation project affecting FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine. 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, and food composition and nutrition. JIFSAN also encompasses other agency programs such as cosmetics, dietary supplements, and food labeling.

IV. Purpose

Supplemental funding to FDA's current cooperative agreement will provide the UMCP with the necessary resources to conduct further research related to the goals of the National Food Safety Initiative and to leverage additional resources for applied nutrition, animal health science activities, and other agency programs. These resources would: (1) Expand the expertise for public health research and risk assessment initiatives, (2) support the Risk Assessment Consortium, and (3) increase innovative public/private research and education partnerships. Because international safety regulations must be founded on science-based risk assessments, FDA's scientists must have a lead role in their development.

Additionally, supplemental funding will provide resources to identify gaps in risk analysis to: (1) Minimize/reduce uncertainty in risk management decisions; (2) improve the quality of risk assessments applied to agency programs, principally but not limited to food safety and applied nutrition (e.g., microbial pathogens, natural toxins, chemical contaminants, and food composition and nutrition); and (3) enhance risk communication, through outreach and public information programs, that will help the mass media and consumers understand and act on public health concerns. Innovative research and outreach efforts, made possible by the supplemental funding, will complement existing efforts under FDA's current cooperative agreement with the UMCP and will provide public health officials with the appropriate knowledge to formulate regulatory decisions and enhanced capabilities to communicate with their stakeholders.

V. Substantive Involvement by FDA

All terms and conditions of the current award shall remain in full force and effect for the supplemental awards.

VI. Review Procedure

The application submitted by the UMCP will undergo a noncompetitive, dual peer review. The application will be reviewed for scientific and technical merit by a panel of experts based on applicable evaluation criteria. If the application is recommended for approval it will then be presented to the National Advisory Environmental Health Sciences Council.

VII. Reporting Requirement

All terms and conditions of the current award shall remain in full force and effect for the supplemental awards.

VIII. Mechanism of Support

Support will be in the form of supplements to FDA's cooperative agreement with the UMCP. This agreement will be subject to all policies and requirements that govern the research grant program of the Public Health Service, including provisions of 42 CFR part 52 and 45 CFR part 74.

Dated: July 15, 1999



William K. Hubbard
Senior Associate Commissioner for
Policy, Planning and Legislation

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