

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**Cooperative Agreement to Support the World Health Organization International Programme on Chemical Safety; Notice to Accept and Consider a Single Source Application; Availability of Funds for Fiscal Year 2002; RFA-FDA-CFSAN-02-2**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is announcing its intent to accept and consider a single source application for the award of a cooperative agreement to the World Health Organization (WHO) to support the International Programme on Chemical Safety (IPCS). FDA anticipates providing \$140,000 (direct and indirect costs) in fiscal year 2002 in support of this project. Subject to the availability of Federal funds and successful performance, two additional years of support up to \$140,000 per year (direct and indirect costs) will be available.

The cooperative agreement assures FDA's participation in important international standard setting activities for food ingredients, contaminants, and veterinary drug residues which provides the public with greater assurance of the quality and safety of food sold in the United States.

**DATES:** Submit applications by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Application forms are available from, and completed applications should be submitted to: Rosemary Springer, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7182. If an application is hand-carried or commercially delivered, it should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857, FAX 301-827-7101. Application forms can also be found at

[http://www.nih.gov/grants/phs398/forms\\_\\_toc.html](http://www.nih.gov/grants/phs398/forms__toc.html). Do not send the application to the Center for Scientific Review, National Institutes of Health (NIH). An application not received by FDA in time for orderly processing will be returned to the applicant without consideration. FDA can not receive an application electronically.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the administrative and financial management aspects of this notice:* Rosemary Springer (see **ADDRESSES**), e-mail: [rspringe@oc.fda.gov](mailto:rspringe@oc.fda.gov).

*Regarding the programmatic aspects:* Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3083, e-mail: [Mitchell.Cheeseman@CFSAN.fda.gov](mailto:Mitchell.Cheeseman@CFSAN.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

FDA is announcing its intention to accept and consider a single source application from the WHO to support the International Programme on Chemical Safety. FDA's authority to enter into grants and cooperative agreements is detailed 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. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public. This application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100).

**II. Background**

Under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), premarket approval is required for food additives intended for direct addition to food. FDA grants approval for the use of such food additives by issuance of a regulation prescribing the conditions

under which the additive may be safely used, including any specifications regarding identity or purity that the additive must meet.

New animal drugs also require premarket approval under section 512 of the act (21 U.S.C 360b). As with food additives, FDA establishes appropriate limitations and specifications for the use of animal drugs.

Since the early 1980s, FDA has provided support for the WHO International Programme on Chemical Safety.

IPCS is a cooperative venture of three United Nations agencies: WHO, International Labor Organization (ILO), and the United Nations Environmental Programme (UNEP). WHO is the executing agency and manages the Central Unit in Geneva.

The IPCS organizational setting provides an umbrella that allows for timely collaboration in undertaking multinational cooperative activities, which is an important step in serving the world community.

The various programs under the International Programme on Chemical Safety significantly contribute in the development of international standards. An important program under IPCS is the Food and Agriculture Organization/WHO Joint Expert Committee on Food Additives (JECFA), which is the scientific advisory body to the Codex Alimentarius Commission for food additives, contaminants, and residues of veterinary drugs in food. Relevant standards, guidelines, and recommendations for food additives, contaminants, and veterinary drug residues established by the Codex Alimentarius Commission are specifically recognized by the World Trade Organization (WTO) as necessary to protect human health, and are presumed to be consistent with the 1994 Uruguay Round of the General Agreement on Tariffs and Trade (GATT). GATT requires that countries consider Codex standards when establishing measures to ensure food safety.

Since its inception in 1962, FDA has participated in the standard-setting activities of the Codex Alimentarius Commission, including developing standards for food additives, contaminants, and veterinary drug residues. The result of this interaction has been to maintain the high safety standard

for foods entering the United States from abroad and to facilitate trade between the United States and the 164 other countries that participate in the development of, and recognize, Codex standards. It is important that FDA continues to participate in such standard development in order to maintain input into the development of appropriate scientific standards for the protection of the safety of food ingredients and to share information on the development of such standards around the world.

FDA's participation in international harmonization and international standard setting activities enhances the Agency's ability to achieve international standards that are favorable; ensures that the safety of the U.S. food supply is not compromised by inadequate international standards; and promotes the safe use of food additives in foods in international trade and thereby enhances the safe use of food additives in imported food. Participation in international standard setting activities also reduces the likelihood of challenges involving food additives being brought before WTO either by the U.S. Government or against the U.S. Government.

### **III. Objectives**

The following activities to be supported by this cooperative agreement are:

1. Schedule, plan, and conduct appropriate work groups and committee meetings, which have emphasis on food additives and contaminants, and the evaluation of residues in veterinary drugs in food.
2. Identify advisers and prepare working papers summarizing the data on substances under consideration.
3. Prepare written working papers and technical documents for JECFA, for the Codex Committee on Food Additives and Contaminants, and for the Codex Committee on Residues of Veterinary Drugs in Food.

### **IV. 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 project

funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

1. FDA will participate as head of the U.S. Delegation in the Sessions of the Codex Committee on Food Additives and Contaminants (CCFAC). This includes participation in all ad hoc working groups associated with CCFAC. This participation includes, but is not limited to, serving as chair for the CCFAC ad hoc Working Group on the General Standard for Food Additives (GSFA), and the CCFAC ad hoc Working Group on Specifications, and participating in the CCFAC's ad hoc Working Group on Contaminants and Toxins.

2. FDA will participate in the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF). Current participation includes, but is not limited to, chair of CCRVDF and head of the U. S. Delegation to CCRVDF.

3. FDA will provide official comments to the Codex Secretariat on discussion documents, position papers, draft Codex standards, and other documents associated with CCFAC and CCRVDF that are circulated for comment. FDA will ensure that these comments are consistent with current agency policy on the use of food additives and the presence of contaminants in food (CCFAC), and on the presence of veterinary drug residues in food (CCRVDF).

4. FDA will work closely with the Codex Secretariat to provide, as needed, in accordance with charges given to the U.S. Delegation by CCFAC or CCRVDF, expert assistance in the timely development of Codex documents, which may include, but are not limited to, technical documents (e.g., associated with Meeting Reports of CCFAC and/or CCRVDF), databases, and draft Codex Standards (e.g., GSFA).

5. FDA will provide expert advice to FAO/WHO JECFA. This advice may include, but is not limited to, the areas of food additive specification development, estimation of intake of food additives and contaminants, risk assessment, and safety assessment of food additives, contaminants, and veterinary drug residues in food.

## V. Availability of Funds

It is anticipated that FDA will fund this cooperative agreement at a level of approximately \$140,000 for the first year. An additional 2 years of support will be available, depending upon fiscal year appropriations, and successful performance.

## VI. Reasons for Single-Source Selection

Competition is limited to WHO/IPCS because it is the parent organization of JECFA, which provides scientific advice to the Codex Alimentarius Commission. The international food standards established by the Codex Alimentarius Commission are recognized by WTO as necessary to protect public health and presumed to be consistent with the Sanitary and Phytosanitary Agreement of GATT. These programs under IPCS are the only such programs in existence and make IPCS unique as a participant in international standard setting for food ingredients, contaminants, and veterinary drug residues. Awarding this cooperative agreement will ensure that the risk assessments provided by JECFA to the Codex Alimentarius Commission are science-based, ensure that food sold in the United States is safe, and enhance the safe use of food additives in imported food.

## VII. Submission Requirements

The original and two copies of the completed grant application form PHS 398 (rev. 5/01) with copies of the appendices for each of the copies, should be submitted to Rosemary Springer (see **ADDRESSES**). The outside of the mailing package should be labeled "Response to RFA-FDA-CFSAN-02-2". The application will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before [*insert date 30 days after date of publication in the **Federal Register***]. Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the Public Health Service (PHS) to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925-0001.

## **VIII. Reporting Requirements**

An annual financial status report (FSR) (SF-269) is required. The original and two copies of the report must be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the grant. Failure to file FSR in a timely fashion will be grounds for suspension or termination of the grant.

An annual program progress report is also required. The noncompeting continuation application (PHS 2590) will be considered the annual program progress report.

A final program progress report, FSR (SF-269), and invention statement must be submitted within 90 days after the expiration of the project period as noted on the notice of grant award.

## **IX. Review Procedures and Evaluation Criteria**

### *A. Review Procedures*

The application submitted by WHO/ IPCS will first be reviewed by grants management and program staff for responsiveness. The requested budget must not exceed \$140,000 (direct and indirect costs). The application will be considered nonresponsive if it is not in compliance with this document. If an application is found to be nonresponsive, it will be returned to the applicant without further consideration.

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

### *B. Review Criteria*

The application will be reviewed and evaluated according to the following criteria:

1. The application clearly demonstrates an understanding of the purpose and objectives of the cooperative agreement regarding the safety of food ingredients, contaminants, and veterinary drug residues.
2. The application clearly describes the steps and a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the cooperative agreement. The application presents a clear plan and schedule of steps to accomplish the goals of the cooperative agreement.
3. The application establishes the applicant's ability to perform the responsibilities under the cooperative agreement including the availability of appropriate staff and sufficient funding.
4. The application specifies the manner in which interaction with FDA will be maintained throughout the lifetime of the project.
5. The application specifies how IPCS will monitor progress of the work under the cooperative agreement and how progress will be reported to FDA.
6. The application shall include a detailed budget that shows: (1) Anticipated costs for personnel, travel, communications and postage, equipment, and supplies; and (2) the sources of funds to meet those needs.

## **X. Mechanism of Support**

Support for this project will be in the form of a cooperative agreement. This agreement will be subject to all policies and requirements that govern the research grant programs of PHS, including provisions of 42 CFR part 52, 45 CFR parts 74 and 92, and PHS's grants policy statement. The regulations issued under Executive Order 12372 do not apply. The length of support will be 1 year with the possibility of an additional 2 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. The NIH modular grant program does not apply to this FDA program.