

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-[ ]" (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