DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ruminant Feed Ban Support Project; Availability of Cooperative Agreements under a Limited Competition; Request for Applications: RFA-FD-08-008; Catalog of Federal Domestic Assistance Number: 93.449

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR) in coordination with the Center for Veterinary Medicine (CVM), is announcing the availability of cooperative agreements to further enhance the infrastructure of State, territorial, and tribal animal feed safety and bovine spongiform encephalopathy (BSE) prevention programs. These cooperative agreements are intended to fund additional personnel, equipment, supplies, and training to support activities related to the FDA ruminant feed ban (21 CFR part 589.2000) (referred to as the BSE/ruminant feed ban), in State, territory, and tribal governments.

Under these cooperative agreements, the State, territory, and tribal governments would enhance their feed/BSE safety programs to increase the ability to locate and visit firms involved in the manufacture, distribution, and transportation of animal feed and operations feeding ruminant animals in their jurisdiction, to verify compliance with the BSE/ruminant feed ban. In addition, funds could be used to increase State, territory, and tribal personnel dedicated to conducting these inspections. Funds could be used for supplies, training, and laboratory equipment for feed sample testing using FDA validation methods. Funds could also be used to conduct educational outreach activities and to develop materials needed to further and enhance the industries' knowledge of and compliance with the BSE/ruminant feed ban.

The goal of enhancing their feed/BSE safety programs is to increase State, territory, and tribal inspections under section 702 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 372) of renderers, protein blenders, and feed mills that manufacture animal feeds and feed ingredients, and inspections of salvagers of food and feed, and transporters of animal feed and feed ingredients utilizing materials prohibited under the BSE/ruminant feed ban. Finally, the Feed Ban Support Project funds are

intended to supplement, not replace, State funding for program improvement.

There are eight key project areas identified for this effort:

- Hire and/or train State/territory/tribal personnel to conduct BSE/ruminant feed ban inspections. Training of State/territory/tribal personnel may be accomplished through the ORA University, or the Association of American Feed Control Officials Annual Feed Seminar, or other training that meets State/territory/tribal and FDA requirements. New hires for this program must meet the State/territory/tribal agency's qualifications for feed inspections and sampling techniques.
- Hire and/or train laboratory personnel to verify that feed samples are free of materials prohibited under the BSE/ruminant feed ban. Laboratory analyses must utilize FDA methodologies for detection of prohibited materials.
- Identify and inspect renderers, protein blenders, commercial animal feed manufacturers, feed salvagers, distributors (including retailers), transporters of animal feed and feed ingredients, on-farm animal feed mixers, and ruminant feeders within the State/territory/tribal jurisdiction where such firms have

not already been identified and/or inspected for compliance with the BSE/ruminant feed ban. These inspections would be conducted under section 702 of the FD&C Act using and completing the FDA Ruminant Feed Ban Inspection Checklist and Ruminant Feed Ban Compliance Program to verify compliance with the BSE/ruminant feed ban. These inspections would be conducted by officers and employees duly commissioned by FDA in accordance with section 702 of the FD&C Act.

- Conduct surveillance sampling of renderers, protein blenders, and feed mills that manufacture with materials prohibited under the BSE/ruminant feed ban. Sample feeds formulated without prohibited material. A minimum of one sample from each facility would be obtained during the inspection and would be analyzed by the State/territorial/tribal government for prohibited materials. This surveillance sampling would be conducted under section 702 of the FD&C Act using and completing the FDA Ruminant Feed Ban Inspection Checklist and Ruminant Feed Ban Compliance Program to verify compliance with the BSE/ruminant feed ban. This surveillance sampling would be conducted by officers and employees duly commissioned by FDA in accordance with section 702 of the FD&C Act.

- Provide copies of all completed FDA Ruminant Feed Ban Inspection Checklists and sample results as a part of the mid-year program progress report to the FDA Project officer or designated office, as well as provide completed checklists and sample results in accordance with section 702 of the FD&C Act.
- Be able to identify and quantify improvements to the existing State/territory/tribal BSE/ruminant feed ban program or developing new programs (i.e., personnel hiring, personnel training, equipment upgrades, increase in inspections conducted) in the mid-year report as a result of the cooperative agreement.
- Conduct educational outreach activities and develop materials needed to further and enhance the industries' knowledge of and compliance with the BSE/ruminant feed ban.

FDA will support the projects covered by this notice under the authority of Section 311 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107-188), which amends the FD&C Act by adding section 909 (21 U.S.C. 399). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.449.

1. Background

The events of September 11, 2001, reinforced the need to enhance the security and safety of the U.S. food supply. Congress responded by passing the Bioterrorism Act which President Bush signed into law on June 12, 2002. The Bioterrorism Act is divided into the following five titles:

- Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies
- Title II—Enhancing Controls on Dangerous Biological Agents and Toxins
- Title III—Protecting Safety and Security of Food and Drug Supply
- Title IV—Drinking Water Security and Safety
- Title V—Additional Provisions

Subtitle A of Title III—Protection of Food Supply, Section 311—Grants to States for Inspections, amends the FD&C Act by adding section 909 to authorize the Secretary of Health and Human Services to award grants to States, territories, and Indian tribes that undertake examinations, inspections, and investigations, and related activities under section 702 of the FD&C Act. The grant funds are only available for

the costs of conducting these examinations, inspections, investigations, and related activities.

Toward these ends, ORA is offering these cooperative agreements to State/territorial/tribal governments for them to develop new or enhance the capability of their existing BSE/ruminant feed ban programs and assist in an increased surveillance presence throughout the commercial feed channels to prevent the introduction or amplification of BSE in the United States. State/territorial/tribal inspections are based on a determination of compliance of firms with the "Animal Proteins Prohibited In Ruminant Feeds" regulation, (21 CFR 589.2000), as well as any subsequent regulations and guidance applicable to the BSE/ruminant feed ban. This regulation is designed to prevent the establishment and amplification of BSE through animal feed, by prohibiting the use of certain proteins derived from mammalian tissue in the feed of ruminant animals. The regulation affects renderers, protein blenders, commercial animal feed manufacturers, distributors (including retailers), transporters of animal feed and feed ingredients, on-farm animal feed mixers, and ruminant feeders. Based on the need to control the entry and spread of this disease, the agency has set a goal to

assist in the development of new or the enhancement of existing State/territory/tribal BSE/ruminant feed ban programs to help meet compliance with the regulation.

2. Program Goals

The goal of FDA's ORA Cooperative Agreement Program is to enhance, complement, develop and improve State/territory/tribal feed safety and surveillance programs. This will be accomplished through the provision of funding for additional equipment, supplies, funding for personnel, training in current FDA approved feed testing methodologies, participation in proficiency testing to establish additional reliable laboratory sample analysis capacity, and analysis of surveillance samples and State/territorial/tribal compliance inspections. This will also require extensive cooperation and coordination with FDA District Offices to minimize duplication of inspections.

II. Award Information

1. Award Instrument

Support will be in the form of a cooperative agreement. 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:

- FDA assistance and coordination in the sharing of information on the identification and location of all renderers, protein blenders, commercial animal feed manufacturers, distributors (including retailers), transporters of animal feed and feed ingredients, on-farm animal feed mixers, and ruminant feeders known to FDA and the State/territorial/tribal agency.
- FDA assistance in the training of State/territorial/tribal BSE/ruminant feed ban program personnel.
- FDA assistance in the training of State/territorial/tribal laboratory personnel to assess feed sample analytical results with respect to the BSE/ruminant feed ban.
- FDA assistance in the surveillance sampling of renderers, protein blenders, and feed mills that manufacture with materials prohibited under the BSE/ruminant feed ban.

- FDA assistance and cooperation in the location and inspection of other firms of specified concern, such as feed salvagers, feed transporters, and ruminant feeders.
- FDA will assist in the review of all completed checklists and sample results provided as a part of the mid-year reports.
- FDA will assist with joint inspections for training, compliance, auditing or other field activities as requested by the grantee.

2. Applicability

All cooperative agreement projects that are developed at State, territorial, and tribal levels must have existing BSE/ruminant feed ban inspection and surveillance programs or propose in detail the development of a State/territory/tribal BSE/ruminant feed ban regulatory program.

3. Award Amount

The total amount of funding available in Fiscal Year (FY) 2008 is $1 million. Cooperative agreements will be awarded for up to $250,000 in total (direct plus indirect) costs per year for up to two (2) years and can be modified for

year 2, depending on the availability of funds and review of the prior year's accomplishments.

4. Length of Support

The length of support will depend on the nature of the project. For those projects with an expected duration of more than one (1) year, a second year of noncompetitive continuation of support will depend on the following factors: (1) Performance during the preceding year and (2) availability of Federal funds.

5. Funding Plan

It is anticipated that FDA will make up to four awards in FY 2008. The number of projects funded will depend on the quality of the applications received and is subject to availability of Federal funds to support the projects.

In addition, if a cooperative agreement is awarded, grantees will be informed if any additional documentation should be needed to support their award. Funds may be requested in the budget to travel to FDA for meetings with program staff about the progress of the project. The project office will have continuous interaction with the grantee through inspection field audits, collection of mid-

year and end of year progress reports, and provision of training, joint inspections, and compliance. There may be other regular meetings with grantees to assist in fulfilling the requirements of the cooperative agreement.

These cooperative agreements will be made to either fund the development of new State/territory/tribal BSE/ruminant feed ban programs or to enhance existing State/territory/tribal BSE/ruminant feed ban programs for the funding of items such as: supplies, lab equipment, surveillance, sample collection, personnel, for the provision of training in current inspectional and analytical methodology, for the analysis of feed and feed products, and BSE/ruminant feed ban inspections. Successful applications will be selected for funding to ensure a broad geographic distribution of the program. Size of the existing or new State/territory/tribal program and number of facilities to be covered under the cooperative agreement will also be determining factors.

States with current BSE/ruminant feed ban contracts with FDA can maintain these contracts for BSE/ruminant feed ban inspections at the discretion of the State and FDA. However, the facilities and work covered under the contract

cannot be counted towards fulfillment of the cooperative agreement and must remain distinct and separate from the cooperative agreement.

These cooperative agreements are not to fund licensed medicated feed or routine feed safety good manufacturing practice (GMP) inspections that are unrelated to the BSE/ruminant feed ban.

III. Eligibility Information

1. Eligible Applicants

This cooperative agreement program is only available to State, territory, and tribal agency BSE/ruminant feed ban regulatory programs that undertake inspections and related activities under section 702 of the FD&C Act and that are not currently funded under this cooperative agreement.

2. Cost Sharing or Matching

Cost sharing is not required.

3. Other

Dun and Bradstreet Number (DUNS).

As of October 1, 2003, applicants are required to have a DUNS number to apply for a grant or cooperative agreement

from the Federal Government. The DUNS number is a 9-digit identification number that uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

IV. Application and Submission

1. Addresses to Request Application

In order to apply electronically, the applicant must have a DUNS number and register in the Central Contractor Registration (CCR) database as described in section IV.6.A of this document. PLEASE NOTE: You must be registered with a username and password obtained from a Credential Provider to apply for opportunities on Grants.gov. http://www.grants.gov/applicants/get_registered.jsp

FDA is accepting new applications for this program electronically via Grants.gov. Applicants must apply electronically by visiting the Web site http://www.grants.gov and following instructions under "APPLY FOR GRANTS." The required application PHS 424, which

is part of the PHS 5161- 1 form, can be completed and submitted online by selecting Step 1: "Download a Grant Application Package" then by entering the funding opportunity number "RFA-FD-08-008". The "Selected Grant Applications For Download" page will provide you with the additional resources, including downloads for Adobe Reader and PureEdge Viewer as well as the "Instructions & Application" hyperlink.

If you experience technical difficulties with your online submission you should contact either Marc Pitts, Grants Management Specialist, Office of Acquisitions & Grants Services, Division of Acquisition Support and Grants Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7162, Marc.Pitts@fda.hhs.gov or the Grants.gov Customer Support Center by email at support@grants.gov Customer Support Center by phone at 1-800-518-4726.

2. Content and Form of Application

A. General Information

The applicant will be judged on, and must specifically address, the following in the cooperative agreement application:

- Demonstrate the availability of adequately trained BSE/ruminant feed ban program staff and/or the criteria to hire and/or train personnel to conduct BSE/ruminant feed ban inspections.
- Demonstrate the availability of adequately trained laboratory personnel and/or the criteria to hire and/or train laboratory personnel to assess feed sample analytical results with respect to the BSE/ruminant feed ban. Verify that laboratory analyses will utilize FDA accepted tests and methodologies for detection of prohibited materials. Verify that the laboratory analyses will utilize methodologies included in the current FDA sampling assignments.
- Provide a detailed description of the current BSE/ruminant feed ban regulatory program or a detailed proposal to develop a BSE/ruminant feed ban regulatory program, including types of inspections performed, and types and numbers of feed establishments in the State/ territorial/tribal inventory.
- Provide a properly detailed budget that is intended to develop or enhance the BSE/ruminant feed ban program in the State/territory/tribe.

- Provide an accurate count of all feed facilities including renderers, protein blenders, commercial animal feed manufacturers, distributors (including retailers), transporters of animal feed and feed ingredients, on-farm animal feed mixers, and ruminant feeders in their State, territory, or tribal government. Provide an indication of how many of each of these facilities would be covered each year under this agreement.
- Provide a detailed description of how the BSE/ruminant feed ban program inspections and/or feed sampling and analyses are to be performed.
- Provide detailed descriptions of how current, noninspected facilities and/or nonidentified facilities will be identified and added to the State's inspection responsibilities.
- Demonstrate the ability to satisfy the reporting requirements outlined in section VI.3.A of this notice.
- Provide current funding level certification for their existing BSE/ruminant feed ban program from State/territory/tribal funding appropriations.
- Outline detailed methodology for program improvement or program development to accomplish the work.

- Provide justification for hiring new staff, hiring qualifications, their training needs and any new equipment.
- State Territory /tribe BSE/ruminant feed ban grantees should provide a clearly detailed description how the State Food Program will follow procedures for notifying FDA of violative facilities for enforcement under FDA jurisdiction.

B. Laboratory Facilities

The applicant must provide a complete description of the facilities, including the following information: The name and address of the State/territory/tribal facility conducting the feed sample testing; the name of the most responsible individual for the facility where the testing will be conducted; and, the location and installation requirements of any equipment purchased with cooperative agreement funds.

Other facilities information that must be provided includes:

- Operational support areas to be used for the project, including details about the availability of ancillary laboratory safety and support equipment and facilities;
- Details describing the sample receiving and sample storage areas and a description of any existing chain-of-custody procedures;
- A detailed description of the proposed upgrades to existing laboratory facilities to accommodate new equipment including drawings and cost estimates.

Laboratory Management Practices:

For the laboratory, the following management information must be provided:

- A summary description of any quality management system defined, in development, or in place as it relates to quality control and quality assurance procedures and practices;
- A summary description of staffing management, specifically to include feed sample testing abilities and procedures;
- A summary description of procedures in place to monitor feed sample workflow, including the tracking and monitoring of sample analyses in progress to include a

description of the laboratory work product review process. Additionally, the ability to perform and complete the feed sample analyses and provide a report of a sample analysis within a responsive and reasonable timeframe must be described. The grantee shall utilize and follow the laboratory testing procedures, methodology, and protocol employed and accepted by FDA in the assessment of feed samples with respect to the BSE/ruminant feed ban.

In addition, if a cooperative agreement is awarded, grantees will be informed if any additional documentation should be needed to support their award.

C. Format for Application

All applications must be submitted electronically through Grants.gov. Paper applications will not be accepted. The application must be an SF424-PHS-5161. The narrative portion of the application may not exceed 100 pages in length, excluding appendices, and must be single-spaced in 12-point font. The appendices should not exceed 100 pages in length (separate from the narrative portion of the application).

Information collection requirements requested on Form (SF-424)PHS 5161-1, expiration date of January 31, 2009 have been sent by PHS to the Office of Management and Budget (OMB) and have been approved and assigned OMB control number OS-4040-0004.

3. Submission Dates and Times

For FY 08, the application receipt date is [August 8, 2008].

Applications will be accepted from 8 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, until the established receipt date.

All applications must be submitted and received electronically by the close of business on the established receipt date.

No addendum material will be accepted after the established receipt date.

4. Intergovernmental Review

The regulations issued under Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100) apply. Applicants (other than federally recognized Indian Tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert the SPOC to the prospective application(s) and to receive any necessary instructions on the State's review process. A current listing of SPOCs is located at: http://www.whitehouse.gov/omb/grants/spoc.html. The SPOC should send any State review process recommendations to the FDA administrative contact (see AGENCY CONTACTS in section VII of this document). The due date for the State process recommendations is no later than 60 days after the deadline date for the receipt of applications. FDA does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cutoff.

5. Funding Restrictions

These cooperative agreements are not to fund licensed medicated feed or routine feed safety GMP inspections that are unrelated to the BSE/ruminant feed ban. These awards may be only used for the development of new State/territory/tribal BSE/ruminant feed ban programs and to enhance and supplement existing State/territory/tribal BSE/ruminant feed ban program funding. States with current BSE/ruminant feed ban contracts with FDA can maintain these contracts for BSE/ruminant feed ban inspections at the discretion of the State and FDA. However, the facilities and work covered under the contract cannot be counted towards fulfillment of the cooperative agreement and must remain distinct and separate from the cooperative agreement.

6. Other Submission Requirements

A. Central Contractor Registration

Applicants must register with the CCR database. This database is a government wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. Registration with CCR is a mandatory requirement and is consistent with the

government wide management reform to create a citizen-centered web presence and build e-gov infrastructures in and across agencies to establish a "single face to industry." The preferred method for completing a registration is through the World Wide Web at http://www.ccr.gov. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online pre-registration, as well as steps to walk you through the registration process. You must have a DUNS number to begin your registration. The registration process can also be found under the “Organization Registration” page of Grants.gov at: http://www.grants.gov/applicants/organization_registration.jsp

In order to access http://grants.gov an applicant will be required to register with the Credential Provider. Information about this is available at http://www.grants.gov/CredentialProvider.

B. Copyright Material

Applicants and applicants’ sub-grantees and sub-contractors must ensure compliance that any projects developed in whole or in part with Federal funds may be made available to

other State, territorial, local, and tribal BSE/ruminant feed ban regulatory agencies by FDA or its agents. Any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.

V. Application Review Information

1. Criteria

A. General Information

FDA grants management and program staff will review all applications sent in response to this notice. To be responsive, an application must be submitted in accordance with the requirements of this notice and must bear the original signature of the applicant institution’s/organization’s authorized official. Applications found to be nonresponsive will be returned to the applicant without further consideration. Applicants are strongly encouraged to contact FDA to resolve any questions about criteria before submitting their application. Please

direct all questions of a technical or scientific nature to the ORA program staff and all questions of an administrative or financial nature to the grants management staff (see AGENCY CONTACTS in section VII of this document).

B. Scientific/Technical Review Criteria

Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Program criteria will include availability of funds and overall program balance in terms of geography and with respect to existing inventory of feed firms within their State/territory/tribe.

An ad hoc panel of experts in the subject field of the specific application will review applications based on the "Content and Form of Application" requirements listed in section IV.2.A of this document.

A score will be assigned based on the scientific/technical review criteria. The review panel may advise the program staff about the appropriateness of the proposal to the goals of this ORA/Office of Regional Operations (ORO)/DFSR and CVM cooperative agreement program.

C. Program Review Criteria

Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Program criteria will include availability of funds and overall program balance in terms of geography with respect to existing and projected awards.

2. Review and Selection Process

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. Final funding decisions will be made by the Commissioner of Food and Drugs or his designee.

3. Anticipated Announcement and Award

Notification regarding the results of the review is anticipated by September 1, 2008. The expected start date for the FY08 awards will be September 30, 2008.

VI. Award Administration Information

1. Award Notices

The FDA Grants Management Office will notify applicants who have been selected for an award. Awards will either be issued on a Notice of Grant Award signed by the FDA Chief Grants Management Officer or her designee and be sent to successful applicants by mail or be transmitted electronically.

2. Administrative and National Policy Requirements

These agreements will be subject to all applicable policies and requirements that govern the grant programs of PHS, including 45 CFR part 92 and the PHS Grants Policy Statement.

Equipment purchased under this cooperative agreement is subject to the requirements of 45 CFR part 92.31, "Real property."

Applicants must adhere to the requirements of this Notice. Special Terms and Conditions regarding FDA regulatory requirements and adequate progress of the study may be part of the awards notice.

PHS strongly encourages all cooperative agreement 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 designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the "Healthy People 2010" objectives, vols. I and II, for $70 ($87.50 foreign) S/N 017-000-00550-9, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Telephone orders can be placed to 202-512-2250. The document is also available in CD-ROM format, S/N 017-001-00549-5 for $19 ($23.50 foreign) as well as on the Internet at http://www.health.gov/healthypeople. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.) Internet viewers should proceed to "Publications."

3. Reporting

A. Reporting Requirements

The original and two copies of the annual Financial Status Report (FSR) (SF–269) must be sent to FDA's grants management officer within 90 days of the budget period end date of the grant. For continuing cooperative agreements, an annual program progress report is also required. For such cooperative agreements, the noncompeting continuation application (PHS 5161–1) will be considered the annual program progress report.

Mid-year progress reports as well as a final program progress report are required. Mid-year progress reports must contain, but are not limited to the following:

1. Status report on the installation and operational readiness of any analytical equipment that is purchased.
2. Status report on the hiring and training of State/territorial/tribal laboratory personnel.
3. Copies of the inspection report on the firms for which Ruminant Feed Ban Inspection Checklists were completed including general assessment of compliance status.
4. Summary report on the facility inventory that is maintained in the State/territory/tribal government.
5. Status report on the hiring and training of personnel to conduct the inspections.

6. Report on feed sample descriptions and subsequent analytical results.

7. Where the examinations, inspections, or investigations and related activities undertaken under section 702 of the FD&C Act result in a State/territorial/tribal enforcement action, a summary report of the follow-up actions and final resolution of the findings.

8. Summary of improvements (identify and quantify) in the overall State/territory/tribal BSE/ruminant feed ban program resulting from the cooperative agreement.

9. Provide copies of all completed BSE/ruminant feed ban checklists and sample results as a part of the mid-year program progress report to the FDA Project officer or designated office. The grantee must file a final program progress report, FSR, invention statement, and disposition of equipment statement within 90 days after the end date of the project period as noted on the notice of the cooperative agreement award.

B. Monitoring Activities

The program project officer will monitor grantees periodically. The monitoring may be in the form of telephone conversations, e-mails or written correspondence

between the project officer/grants management officer and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official cooperative agreement file and will be available to the grantee upon request consistent with applicable disclosure statutes and FDA disclosure regulations. The grantee organization must comply with all special terms and conditions of the cooperative agreement, including those that state that future funding of the study will depend on recommendations from the project officer. The scope of the recommendation will confirm that: (1) There has been acceptable progress on the project; (2) there is continued compliance with all FDA regulatory requirements; (3) if necessary, there is an indication that corrective action has taken place; and (4) assurance that any replacement of personnel will meet the testing and inspection requirements.

VII. Agency Contacts

For issues regarding the administrative and financial management aspects of this notice: Marc Pitts (see section IV.1 of this document).

For issues regarding the programmatic or technical aspects of this notice: Neal Bataller, Center for Veterinary Medicine, Division of Compliance, Office of Surveillance and Compliance (HFV-235), Food and Drug Administration, 7500 Standish Pl., rm. E441, Rockville, MD 20855, 240-276-9202, e-mail: Neal.Bataller@fda.gov or Jennifer Gabb, Division of Federal-State Relations (HFC-150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, rm. 12-07, Rockville, MD 20857, 301-827-2899, e-mail: jennifer.gabb@fda.hhs.gov or access the Internet at http://www.fda.gov/ora/fedstate/default.htm.

VIII. Other Information

URLs in FDA Grant Applications or Appendices:

All applications and proposals for FDA funding must be self-contained within specified page limitations. Unless otherwise specified in an FDA solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

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 (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services, by a court, or required by another Federal law, 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.

Healthy People 2010:

PHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas.

Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.