DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0369]

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.

SUMMARY: 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 funding 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 support activities related to the FDA ruminant feed ban (referred to as the BSE/ruminant feed ban), in State, territory, and tribal governments. FDA anticipates providing approximately $1 million in direct plus indirect costs in support of this program in fiscal year (FY) 2008. It is anticipated that four awards will be made for up to $250,000 per award per year for up to 2 years.

DATES: The application receipt date is August 8, 2008.

ADDRESSES: Applications may be submitted on or after the opening date and must be successfully received by *http://www.grants.gov*[1] no later than 5 p.m. local time (of the applicant institution/organization) on the application submission/receipt date. If an application is not submitted by the receipt date and time, the application may be delayed in the review process or not reviewed.

The required application, SF–424, can be completed and submitted online. The package should be labeled ''Response to RFA–FDA–08–008''. If you experience technical difficulties with your online submission you should contact Marc Pitts by telephone at 301–827–7162 or by e-mail at *marc.pitts@fda.hhs.gov*.

[1] FDA has verified the non-FDA Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

Paper applications will not be accepted.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Marc Pitts, Office of Acquisitions and Grants Management, Food and Drug Administration (HFA–500), 5630 Fishers Lane, suite 2104, Rockville MD 20857 (see also **ADDRESSES**).

Regarding the programmatic aspects of this notice:Jennifer Gabb, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs, Food and Drug Administration (HFC– 150), 5600 Fishers Lane, Rm. 12– 07, Rockville, MD 20857, 301–827– 2899, e-mail: *jennifer.gabb@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

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 ruminant feed ban. 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 outreach educational activities and materials as needed to further and enhance the industries knowledge and compliance with 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 (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 ruminant feed ban. Finally, the Feed Ban Support Project funds are intended to supplement, not replace, State funding for program improvement.

The following are seven key project areas identified for this effort: (1) Hire and/or train State/territory/tribal personnel to conduct 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; (2) hire and/or train laboratory personnel to verify that feed samples are free of materials prohibited under the ruminant feed ban. Laboratory analyses must utilize FDA accepted methodologies for detection of prohibited materials; (3) 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 that have not already been identified and/or inspected for compliance with the ruminant feed ban. These inspections would be conducted under section 702 of the 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 act; (4) 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 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 act; (5) 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, as well as provide completed checklists and sample results in accordance with section 702 of the act; (6) 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; (7) conduct outreach educational activities and materials as needed to further and enhance the industries knowledge and compliance with ruminant feed ban.

Please visit *http://www.grants.gov* to view the full version of this Request for Applications (RFA). FDA urges applicants to read the full version RFA in its entirety prior to submitting application packets.

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: (1) Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies; (2) Title II—Enhancing Controls on Dangerous Biological Agents and Toxins; (3) Title III—Protecting Safety and Security of Food and Drug Supply; (4) Title IV—Drinking Water Security and Safety; and (5) Title V—Additional Provisions

Subtitle A of Title III—Protection of Food Supply, Section 311—Grants to States for Inspections, amends the 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 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 feeding 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.

II. Project Goals, Definitions, and Examples

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.

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 a determining factor.

These cooperative agreements are not to fund licensed medicated feed or routine feed safety good manufacturing practices (GMP) inspections that are unrelated to the ruminant feed ban. These awards may be only used for the development of new State/ territory/ tribal BSE/ruminant feed ban programs or to enhance and supplement existing State/ territory/tribal BSE/ruminant feed ban program funding. States with current BSE/ruminant feed ban contracts from 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.

III. Reporting Requirements

A final Program Progress Report and a final Financial Status Report (FSR) (SF–269) are required within 90 days of the expiration date of the project period as noted on the Notice of Grant Award. In addition, the grantee must file an 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. An original and two copies of each report shall be submitted to Marc Pitts, Grants Management Office (see ''). The program progress report should include: (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 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; and (9) provide copies of all completed BSE/ruminant feed ban checklists and sample results as a part of the quarterly program progress report to the FDA Project officer or designated office.

A Mid-Year Progress Report is also required no later than 90 days after the close of the budget period. The Mid-Year Progress Report should cover 6 months of activity including all criteria listed in the previous paragraph.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least semi-annually by the project officer. Project monitoring may also be in the form of telephone conversations between the project

officer/grants management specialist and the principal investigator.

When multiple years are involved, awardees will be required to submit the PHS Non-Competing Grant Progress Report SF–424 (5161) application *http://www.hhs.gov/forms/PHS–5161–1.pdf*annually and financial statements as required in the DHHS Grants Policy Statement. Reports must be submitted 2 months prior to the next budget period start date. The Progress Report should include a report of the previous meeting supported by the current grant, as well as a full description of the next planned meeting.

IV. Mechanism of Support

A. Award Instrument

This funding opportunity will use the Research Demonstration Cooperative Agreements (U18) award mechanisms.

This funding opportunity uses just-in-time budget concepts. It also uses the nonmodular budget format. Applicants must complete and submit a detailed categorical budget the SF–424 application.

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.

B. Eligibility

This cooperative agreement program is only available to State/territory/tribal agency feed/BSE regulatory programs that undertake inspections and related activities under section 702 of the act and who are currently not funded under this cooperative agreement.

C. Length of Support

It is anticipated that FDA will fund these grants at a level requested but not exceeding $250,000 total direct plus indirect costs for the first year. An additional year (1) of support up to approximately $250,000 (direct plus indirect costs) per year will be available, depending upon fiscal year appropriations and successful performance. The length of support will also depend on the nature of the project.

D. Funding Plan

Federal funds are currently available from FDA for this program. However, continued funding of a noncompetitive segment is contingent upon satisfactory progress as determined annually by FDA procedures, the receipt of a noncompeting continuation application, final yearly report and the availability of Federal funds. An estimated amount of $1 million is available 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.

V. Review Procedure and Criteria

All applications submitted in response to this request for applications (RFA) will first be reviewed for responsiveness by grants management and program staff. Responsiveness is defined as submission of a complete application packet on or before the required submission date as listed in the previous paragraphs. If applications are found to be nonresponsive, they will be returned to the applicant without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts.

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria before the submission of their application. All technical or programmatic questions must be directed to the ORA program staff (see **ADDRESSES**). All administrative or financial questions must be directed to the Grants Management Staff (see **ADDRESSES**).

VI. Submission Requirements

FDA is accepting new applications for this program electronically via *http:www.grants.gov* (Grants.gov). To download the SF424 application forms for this Funding Opportunity Announcement (FOA), link to ''Apply for Grants'' and follow the directions provided on that site. A one-time registration is required for institutions at Grants.gov, link to ''Get Registered.'' The application receipt date is July 30, 2008.

Your organization will need to obtain a Data Universal Number System (DUNS) number as part of the Grants.gov registration process. The DUNS number is a 9–digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. The Dunn and Bradstreet number can be obtained by calling: 866–705–5711 or through the Web site at *http://www.dnb.com/us/*.

The applicant must also register in the Central Contractor Registration (CCR) database in order to be able to submit the application. Information about the CCR is available at *http://www.ccr.gov* or under the ''Organization Registration'' page of Grants.gov at:*http://www.grants.gov/applicants/organization_registration.jsp*

VII. Method of Application

A. Submission Instructions

The SF–424 (5161) application has several components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov (link to ''Apply for Grants '') includes all applicable components, required and optional.

B. Format for Application

A completed application in response to this FOA includes the data in the following components:

The face page of the application should indicate ''Response to Ruminant Feed Ban Support Project RFA–FDA–08–008.''

For information that should be addressed in the application, please see the full version of this RFA at *http://www.grants.gov*.

VIII. Legend

Unless disclosure is required by the Freedom of Information Act (FOIA) as amended (5 U.S.C. 552), as determined by the Freedom of Information (FOI) officials of the U.S. Department of Health and Human Services (HHS) or by a court, data contained in the portions of an application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted and/or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated: July 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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