Approved But Unfunded Applications

Applications that are approved but unfunded may be held over for funding in the next funding cycle, pending the availability of funds, for a period not to exceed one year.

3. Anticipated Announcement and Award Dates

Subject to the availability of funding, ADD intends to award new grants resulting from this Program Announcement during the fourth quarter of Fiscal Year 2005. Up to $350,000 in Federal funds will be available to support these projects this fiscal year.

For the purpose of the awards under this Program Announcement, the successful applicants should expect a project start date of September 1, 2005.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR part 74 (non-governmental) or 45 CFR part 92 (governmental).

Direct Federal grants, sub-award funds, or contracts under this Family Support Initiative 2005 program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the Equal Treatment For Faith-Based Organizations, which includes the prohibition against Federal funding of inherently religious activities, can be found at either 45 CFR part 87.1 or the HHS Web site at *http://www.os.dhhs.gov/fbci/waisgate21.pdf.*

3. Reporting Requirements

Programmatic Reports: Quarterly.

Financial Reports: Semi-Annually.

Grantees will be required to submit program progress and financial reports (SF–269) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. In addition, final programmatic and financial reports are due 90 days after the close of the project period.

VII. Agency Contacts

Program Office Contact: Joan Rucker, Program Specialist, U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Developmental Disabilities, 370 L'Enfant Promenade, SW., Mail Stop 405–D, Washington, DC 20447. Phone: 202/690–7898. Fax: 202/205–8037. E-mail: *jrucker@acf.hhs.gov.*

Grants Management Office Contact: Tim Chappelle, Grants Officer, U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Developmental Disabilities, 370 L'Enfant Promenade, SW., 8th Floor, Washington, DC 20447. Phone: 202/401–4855. Fax: 202/401–5468. E-mail: *tichappelle@acf.hhs.gov.*

VIII. Other Information

All forms are available online at: *http://www.acf.hhs.gov/programs/ofs/forms/htm.*

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005, applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *www.Grants.gov.* Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

Please reference Section IV.3 for details about acknowledgement of received applications.

Dated: June 24, 2005.

Patricia A. Morrissey,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 05–13096 Filed 6–30–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ruminant Feed Ban Support Project; Availability of Cooperative Agreements: Request for Applications: RFA–FDA–ORA–05–3; 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 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 ruminant feed ban. Funds could be used to increase State, territory, and tribal personnel dedicated to conducting these inspections. Funds could also be used for supplies, training, and laboratory equipment for feed sample testing using FDA validated methods. 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 ruminant feed ban. Finally, the Feed Ban Support Project funds are intended to supplement, not replace, State funding for program improvement.

There are seven key project areas identified for this effort:

- 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.
- 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 methodologies for detection of prohibited materials.
- Identify and inspect 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 within the State/territory/tribal jurisdiction. 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 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 ruminant feed ban. 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 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.
- Locate and inspect other firms of specified concern, such as feed salvagers, feed transporters, and ruminant feeders. 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 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.
- Provide copies of all completed BSE checklists and sample results as a part of the quarterly 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 program or developing new programs (i.e., personnel hiring, personnel training, equipment upgrades, increase in inspections conducted) in the quarterly reports as a result of the cooperative agreement.

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 Feed/BSE 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 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 project 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 program personnel.

• FDA assistance in the training of State/territorial/tribal laboratory personnel to verify that feed samples are free of materials prohibited under the ruminant feed ban.

• FDA assistance in the surveillance sampling of renderers, protein blenders, and feed mills that manufacture with materials prohibited under the 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 quarterly reports.

• FDA will assist with joint inspections for training, compliance, auditing or other field activities as requested by the awardee.

2. Applicability

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

3. Award Amount

The total amount of funding available in Fiscal Year (FY) 2005 is $2 million. Cooperative agreements will be awarded up to $250,000 in total (direct plus indirect) costs per year for up to three (3) years and can be modified for years 2 and 3, depending on the availability of funds and review of 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 1 year, a second or third 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 ten awards in FY 2005. 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 quarterly 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 programs or to enhance existing State/territory/tribal BSE 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 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.

States with current BSE/ruminant feed ban contracts from FDA can maintain these contracts for feed/BSE 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 ruminant feed ban.

III. Eligibility Information

1. Eligible Applicants

This cooperative agreement program is only available to State, territory, and tribal agency feed/BSE regulatory programs that undertake inspections and related activities under section 702 of the FD&C Act.

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

FDA is accepting new applications for this program electronically via Grants.gov. Applicants are strongly encouraged to apply electronically by visiting the Web site *http://www.grants.gov* and following instructions under ''APPLY.'' The required application PHS 424, which is part of the PHS 5161–1 form, can be completed and submitted online. The package should be labeled ''Response to RFA–FDA–ORA–05–3.'' If you experience technical difficulties with your online submission you should contact either Cynthia Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cpolit@oc.fda.gov* or the Grants.gov Customer Response Center for assistance.

To comply with the President's Management Agenda, the Department of Health and Human Services is participating as a partner in the new governmentwide Grants.gov Apply site. Users of Grants.gov will be able to download a copy of the application package, complete it offline, and then upload and submit the application via the Grants.gov site. We request your participation in the Grants.gov project. When you enter the Grants.gov site, you will find information about submitting an application electronically through the site.

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.

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 program staff and/or the criteria to hire and/or train personnel to conduct ruminant feed ban inspections.
- Demonstrate the availability of adequately trained laboratory personnel and the criteria to hire and/or train laboratory personnel to verify that feed samples are free of materials prohibited under the ruminant feed ban. Verify that laboratory analyses will utilize FDA approved tests and methodologies for detection of prohibited materials.
- Provide a detailed description of current feed regulatory program or proposal to develop a feed 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 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 program inspections and/or feed sampling and analyses are to be performed.
- Provide detailed descriptions on 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 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.
- Provide a clearly detailed description how the State/territory/tribe BSE program will follow the procedures set forth in section 702 of the FD&C Act 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 BSE 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 BSE testing abilities and procedures;
- A summary description of procedures in place to monitor BSE 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 BSE analyses and provide a report of a sample analysis within a responsive and reasonable timeframe must be described. At a minimum, the grantee shall utilize and follow the laboratory testing procedures, methodology, and protocol employed and approved by FDA in the testing of all BSE samples to ensure compliance with the 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

Data and information included in the application will generally not be publicly available prior to the funding of the application. After funding has been granted, data and information included in the application will be given confidential treatment to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (including 21 CFR 20.61, 20.105, and 20.106). By accepting funding, the applicant agrees to allow FDA to publish specific information about the cooperative agreement.

Information collection requirements requested on Form PHS 5161–1 (Rev. 7/00) have been sent by PHS to the Office of Management and Budget (OMB) and have been approved and assigned OMB control number 0348–0043.

3. Submission Dates and Times

For FY 05, the application receipt date is August 15, 2005.

Applications will be accepted from 8 a.m. to 4:30 p.m., Monday through Friday, until the established receipt date. Please do not send applications to the Center for Scientific Review (CSR) at the National Institutes of Health (NIH). Any application sent to NIH/CSR that is forwarded to the FDA Grants Management Office and not received in time for orderly processing will be judged nonresponsive and returned to the applicant.

Applications submitted electronically must be received 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.htlm*. 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 ruminant feed ban. These awards may be only used for the development of new State/territory/tribal BSE programs or to enhance and supplement existing State/territory/tribal BSE program funding. States with current BSE/ruminant feed ban contracts from FDA can maintain these contracts for feed/BSE 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

In anticipation of the *http://www.grants.gov* electronic application process, applicants must register with the CCR database. This database is a governmentwide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. Registration with CCR will eventually become a requirement and is consistent with the governmentwide 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.

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.grant.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 feed/BSE 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).

The original signature requirement does not apply to applications submitted electronically.

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.

The ad hoc expert panel 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, 2005. The expected start date for the FY 05 awards will be September 29, 2005.

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 (PHS 5152) signed by the FDA Chief Grants Management Officer 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.healthypeople.gov/*. (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.

Quarterly progress reports as well as a final program progress report are required. Quarterly 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 followup actions and final resolution of the findings.
8. Summary of improvements (identify and quantify) in the overall State/territory/tribal BSE program resulting from the cooperative agreement.
9. Provide copies of all completed BSE checklists and sample results as a part of the quarterly 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: Cynthia Polit (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 Steve Toigo, Division of Federal-State Relations (HFC–150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, e-mail: *steve.toigo@fda.gov* or access the Internet at *http://www.fda.gov/ora/fed_state/default.htm*.

VIII. Other Information

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.

Dated: June 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–13114 Filed 6–29–05; 9:03 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 21, 2005, from 8 a.m. to 6:30 p.m.

Location: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 21, 2005, in the morning, the committee will hear updates on the following topics: (1)