

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Research Studies on Microbiological Hazards Associated With the Food Animal Production Environment; Availability of Cooperative Agreements; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) is announcing the availability of research funds for fiscal year (FY) 2000 to study the microbiological hazards associated with the food animal production environment. Approximately \$600,000 will be available in FY 2000. FDA anticipates making 3 or 6 Cooperative Agreement awards at \$100,000 to \$200,000 per award per year (direct and indirect costs combined). Support for these agreements may be for up to 3 years. The number of agreements funded will depend on the quality of the applications received and the availability of Federal funds to support the projects.

DATES: Submit letters of intent as soon as possible or by [*insert date 45 days after date of publication in the Federal Register*]. Submit applications by [*insert date 60 days after date of publication in the Federal Register*]. If the date falls on a weekend or on a holiday, the date of submission will be extended to the following workday.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Cynthia M. Polit, Grants Management Specialist (HFA-520), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301-827-7180. Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA-520), rm. 2129, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Cynthia M. Polit (address above).

Regarding the programmatic aspects of this notice: David B. Batson, Office of Research, Center for Veterinary Medicine (HFV-502), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301-827-8021.

SUPPLEMENTARY INFORMATION: FDA's CVM is announcing the availability of funds for FY 2000 for awarding cooperative agreements to support research studies on microbiological hazards associated with the food animal production environment. FDA will support the research studies covered by this notice under section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free work place 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.

PHS urges applicants to submit work plans that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, stock No. 017-00100474-0) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, 202-512-1800.

I. Background

FDA is mandated to ensure the microbiological safety of foods, including those derived from animals. The President's Food Safety Initiative (FSI) of 1997 calls for increased allocation of resources for research by FDA to identify and investigate microbiological hazards associated with food produced by animal agriculture. Even though the American food supply is among the safest in the world, millions of Americans are stricken by illness each year caused by the food they consume and some 5,000 a year, primarily the very young and elderly, die as a result. The goal

of the FSI is to further reduce the incidence of foodborne disease to the greatest extent possible. Specifically, FSI mandates research be conducted to develop the means to: (1) Identify and characterize more rapidly and accurately foodborne hazards, (2) provide the tools for regulatory enforcement, and (3) develop interventions that can be used as appropriate to prevent hazards at each step from production to consumption of food.

The role of FDA's CVM in this research relates to microbial hazards associated with pre-harvest phases of food animal production, including aquaculture. The FSI specifically identifies a need for research addressing the effect(s) of therapeutic and nontherapeutic antimicrobial use in food producing animals on commensal and foodborne bacterial pathogens. This research will include: (1) Investigations of factors associated with the emergence, transmission, and carriage of human foodborne pathogens in or on food-producing animals and edible products derived from them; and (2) investigations of the microbiological consequences of antimicrobial use in the animal production environment, including selection and elaboration of antimicrobial resistant foodborne pathogens and possible interactions that would create conditions for increased pathogen carriage rates.

II. Research Goals and Objectives

The specific objective of this research program will be to stimulate research on microbiological hazards associated with the food animal production environment. It is of particular interest to FDA that this research advance scientific knowledge of human foodborne pathogens, such as *Salmonellae*, *Escherichia coli*, and *Campylobacter*. Potential areas of investigation include: (1) Antimicrobial resistance development and dissemination in the animal production environment, (2) approaches to mitigate or minimize antimicrobial resistance, and (3) the impact of antimicrobial drug use on the carriage of foodborne pathogens and sentinel microorganisms used for monitoring programs.

Projects that fulfill anyone or a combination of the following specific objectives will be considered for funding:

1. Studies on the development, dissemination, transmission, and persistence of antibiotic resistant bacteria and/or genetic determinants from these bacteria in the animal production environment. The horizontal transmission of antimicrobial resistant bacteria and resistance genes in the animal and animal production environment is of special interest. Also, the persistence of antimicrobial resistant foodborne pathogens and/or genes in the animal production environment after withdrawal of antimicrobials is of special interest. FDA's CVM is interested in research in all food-producing animal species, but is especially interested in poultry and the poultry production environment.

2. Research on the mitigation/intervention strategies to decrease or minimize antimicrobial resistance in the animal production environment through the manipulation of drug use, altering drug dosage, use of competitive exclusion products, and/or rotation of antimicrobials used in beef cattle, dairy cattle, swine, poultry, and aquaculture.

3. The effect of antimicrobial use on the carriage and/or shedding of foodborne pathogens (i.e., pathogen load) in the above listed animal species.

FDA anticipates funding at least one cooperative agreement for each of the objectives listed above contingent upon the quality of the application submissions and the availability of FY 2000 funding.

III. Reporting Requirements

A Program Progress Report and a Financial Status Report (FSR) (SF-269) are required. An original FSR and two copies shall be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the cooperative agreement. Failure to file the FSR (SF-269) on time will be grounds for suspension or termination of the grant. Progress reports will be required quarterly within 30 days following each Federal fiscal quarter (December 31, March 31, June 30, September 30), except that the fourth report that will serve as the annual report and will be due 90 days after the budget expiration date. CVM program staff will advise the recipient of the suggested format for the Program Progress Report at the appropriate time. A final FSR

(SF-269), Program Progress Report and Invention Statement must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least quarterly by the Project Officer and the Project Advisory Group. Project monitoring may also be in the form of telephone conversations between the Project Officer/Grants Management Specialist and the Principal Investigator and/or a site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be duly recorded in the official file and may be available to the recipient upon request.

IV. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of cooperative agreements. These cooperative agreements will be subject to all policies and requirements that govern the research grant programs of PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations promulgated under Executive Order 12372 do not apply to this program.

B. Eligibility

These cooperative agreements are available to any public or private nonprofit entity (including State and local units of government) and any for-profit entity. For-profit entities must commit to excluding fees or profit in their request for support to receive awards. Organizations described in section 501(c)(4) of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive awards.

C. Length of Support

The length of support will be for up to 3 years. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year, and (2) the availability of Federal FY appropriations.

V. Delineation of Substantive Involvement

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will have a substantive involvement in the programmatic activities of all the projects funded under this request for applications (RFA). Substantive involvement includes but is not limited to the following:

1. FDA will appoint Project Officers who will actively monitor the FDA supported program under each award.
2. FDA will establish an Project Advisory Group, which will provide guidance and direction to the Project Officer with regard to the scientific approaches, and methodology that may be used by the investigator.
3. FDA scientists will collaborate with the recipient and have final approval on experimental protocols. This collaboration may include protocol design, data analysis, interpretation of findings, and co-authorship of publications.

VI. Review Procedure and Criteria

A. Review Method

All applications submitted in response to this RFA's will first be reviewed by grants management and program staff for responsiveness to this RFA. 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 in the subject field of the specific application. Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence with the recommendations made by the first level reviewers, and the final funding decisions will be made by the Commissioner of Food and Drugs or her designee.

B. Program Review Criteria

Applicants are strongly encouraged to contact the FDA to resolve any questions regarding criteria or administrative procedure prior to the submission of their application. All questions of a technical or scientific nature must be directed to the CVM contact person and all questions of an administrative or financial nature must be directed to the Grants Management Specialist (see **FOR FURTHER INFORMATION CONTACT** section of this document). Responsiveness will be based on the following criteria:

1. Research should be proposed on microbiological hazards research that is within one or more of the three objectives listed in section II of this document;
2. The proposed study is within the budget and costs have been adequately justified and fully documented;
3. The rationale for the proposed study is sound and the study design is appropriate to address the objectives of the RFA;
4. Laboratory and associated animal facilities are available and adequate;
5. Support services, e.g., biostatistical, computer, etc. are available and adequate; and
6. The Principal Investigator and support staff have research experience, training and competence.

VII. Submission Requirements

The original and five copies of the completed Grant Application Form PHS 398 (Rev. 4/98), or the original and two copies of the PHS 5161 (Rev. 6/99) for State and local governments, with copies of the appendices for each of the copies, should be delivered to the Grants Management Office (address above). State and local governments may choose to use the PHS 398 application form in lieu of the PHS 5161. Submit applications by [*insert date 60 days after date of publication in the **Federal Register***]. If the closing date falls on a weekend or if the date falls on a holiday, the submission date will be extended to the following workday. No supplemental or addendum

material will be accepted after the receipt date. The outside of the mailing package and item 2 of the application face page should be labeled “Response to RFA FDA CVM-00-1”.

VIII. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows program staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be submitted to David B. Batson (address above) by the letter of intent receipt date listed in the **DATES** section of this document.

IX. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH). Any application that is sent to the NIH, not received in time for orderly processing,

will be deemed nonresponsive and returned to the applicant. Instructions for completing the application forms can be found on the NIH home page on the Internet at <http://www.nih.gov/grants/phs398/phs398.html>; the forms can be found at <http://www.nih.gov/grants/phs398/forms-toc.html>. However, as noted above, applications are not to be mailed to the NIH. Applicants are advised that the FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by the NIH on its applications. Applications must be submitted via mail or hand delivery as stated above. FDA is unable to receive applications through the Internet.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98). All “General Instructions” and “Specific Instructions” in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to the CSR, NIH. Applications from State and local governments may be submitted on Form PHS 5161 (Rev. 6/99) or Form PHS 398 (Rev. 4/98).

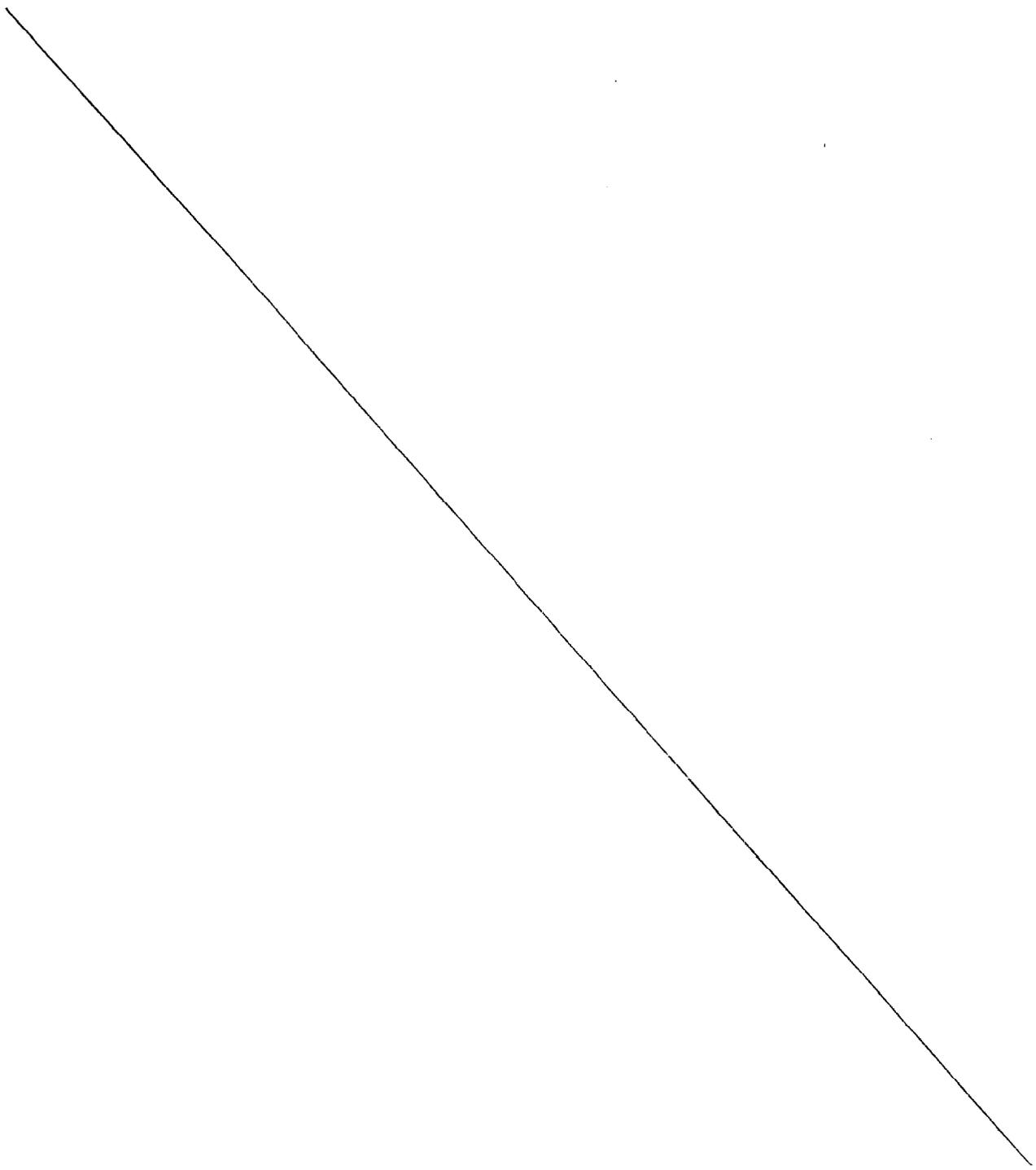
The face page of the application should reflect the request for applications number RFA–FDA–CVM–00–1.

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

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

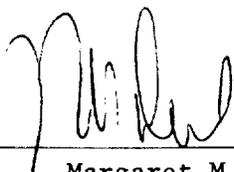
C. Legend

Unless disclosure is required by the FOIA as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which 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: 2/8/00
February 8, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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