

(5) Letters of support from community-based organizations indicating their support of the project and their interest in participating in the project. (15 points)

Applications must be postmarked or, if not sent by U.S. mail, received at the Office of Grants Management no later than the close of business on June 15, 1998. Private metered postmarks will not be acceptable as proof of timely mailing. Applications which are postmarked later than June 15, 1998 will be judged late and will not be accepted for review. (Applicants should request a legibly dated postmark from the U.S. Postal Service.) Applications which do not conform to the requirements of this program announcement or do not meet the applicable regulatory requirements will not be accepted for review. Applicants will be so notified, and the applications will be returned.

Grant Award

The grant will be funded in annual increments (budget periods). The project may be funded for up to three (3) years. Funding for all approved budget periods beyond the first year is contingent upon the availability of funds, satisfactory progress of the project, and adequate stewardship of federal funds.

Review Under Executive Order 12372

Applicants under this announcement are subject to the review requirements of Executive Order 12372, Intergovernmental Review of Department of Health and Human Services Programs and Activities, as implemented by 45 CFR part 100. As soon as possible, the applicant should discuss the project with the State Single Point of Contact (SPOC) for each State to be served. The application kit contains the currently available listing of the SPOCs which have elected to be informed of the submission of applications. For those States not represented on the listing, further inquiries should be made to the Governor's office of the pertinent states for information regarding the review process designated by their state or the SPOC for the state in question.

SPOC comments must be received by the Office of Grants Management 30 days prior to the funding date to be considered.

When the final funding decision has been made, each applicant will be notified by letter of the outcome of its application. The official document notifying an applicant that a project application has been approved for funding is the Notice of Grant Award, which specifies to the grantee the amount of money awarded, the

purposes of the grant, and terms and condition of the grant award.

Dated: April 8, 1998.

James Randolph Farris,

Regional Health Administrator.

[FR Doc. 98-11688 Filed 5-1-98; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Injury Research Grant Review Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Injury Research Grant Review Committee (IRGRC).

Time and Date: 6:30 p.m.-9 p.m., June 6, 1998; 8 a.m.-5 p.m., June 7, 1998.

Place: Renaissance Atlanta Hotel-Downtown, 590 West Peachtree Street, NW, Atlanta, Georgia 30308.

Status: Open: 6:30 p.m.-7 p.m., June 6, 1998. Closed: 7 p.m.-9 p.m., June 6, 1998, through 5 p.m., June 7, 1998.

Purpose: This committee is charged with advising the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the scientific merit and technical feasibility of grant applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focus on prevention and control and to support injury prevention research centers.

Matters To Be Discussed: Agenda items include announcements, discussion of review procedures, and review of grant applications.

Beginning at 7 p.m., June 6, through 5 p.m., June 7, the Committee will meet to conduct a review of grant applications. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92-463.

Agenda items are subject to change as priorities dictate.

Contact Person For More Information: Richard W. Sattin, M.D., Executive Secretary, IRGRC, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, M/S K58, Atlanta, Georgia 30341-3724, telephone 770/488-4580.

Dated: April 27, 1998.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-11715 Filed 5-1-98; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Research Studies to Support Microbial Risk Assessment Modeling; Availability of Cooperative Agreements; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is announcing the availability of approximately \$800,000 for research funds for fiscal year (FY) 1998 to conduct research to support the development of risk assessment dose-response models for microbiological hazards associated with food. FDA anticipates making two to three awards at \$250,000 to \$400,000 (direct and indirect costs) per award per year. Support of these agreements may be 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 project. After the first year, 2 additional years of noncompetitive support are predicated upon performance and the availability of Federal FY funds.

DATES: Submit applications by June 18, 1998. If the closing date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Robert L. Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, Park Bldg., 5600 Fishers Lane, rm. 3-40, Rockville, MD 20857, 301-443-6170. Applications hand-carried or commercially delivered should be addressed to Park Bldg., 12420 Parklawn Dr., rm. 3-40, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of

this notice: Robert L. Robins
(address above).

Regarding the programmatic aspects of this notice: Wes R. Long, Food Safety Initiative Risk Assessment Lead, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-301), 200 C St. SW., Washington, DC 20204, 202-205-4064.

SUPPLEMENTARY INFORMATION: FDA will support the research studies covered by this notice under section 301 of the Public Health Service 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 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.

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. 017-0010-0474-0) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, 202-512-1800.

I. Background

FDA is mandated by the President's Food Safety Initiative (FSI) to develop risk assessment tools to help assure the microbiological safety of foods. 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 9,000 Americans a year, primarily the very young and elderly, die as a result. The goal of FSI is to further reduce the incidence of food borne disease to the greatest extent possible. Risk assessment helps promote this goal by determining the likelihood that exposure to a hazard, such as a food borne pathogen, will result in harm or disease. Risk assessment methods help characterize the nature and size of risks to human health associated with food borne hazards and assist regulators in making decisions about where in the food chain to allocate public resources to reduce those risks that have the greatest consequences for human health. Carefully formulated risk assessments based on the best available data generated from research lead to more informed risk management and better decisions. The President's FSI requires that 1998 funds be used to develop better data and modeling techniques to

assess the exposure of the population to microbial contaminants and the range of health consequences of that exposure.

Research is needed to develop improved methods and models that will make it possible to perform quantitative microbial risk assessments to the degree of complexity needed for most food-safety issues. Such research requires an integration of work in the biological sciences, predictive microbiology, and applied mathematics. Risk assessment's FSI activities focus on developing models for improving risk assessments. Fundamentally, however, additional data is needed to assist in the development of these models. For dose-response models—that is, determining the quantity of a virulent organism ingested and the likely outcome of that event—there are numerous data needs. Risk assessors have mostly relied on qualitative or semi-quantitative criteria, such as outbreak reports or surveillance data, to develop these models. Significant improvements in modeling dose-response relationships for the human population could be realized from a coordinated research effort that leverages completed, ongoing, or planned human clinical trials funded by the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), the Department of Defense (DOD), and others and emphasizes expansion of clinical studies to include the acquisition of data needed in the areas of dose-response relationships at low-dose levels, assessment of potential biomarkers of infection caused by food borne pathogens, and the effects of food matrices on dose-response; also the development of correlative dose-response data from relevant animal surrogates.

II. Research Goals and Objectives

The specific objective of this program of research will be to conduct research to complement the use, development, or improvement of dose-response models for use in risk assessment.

Applications that fulfill the following specific project objectives will be considered for funding. Collaborations among researchers with complementary capabilities are encouraged.

A. Project Objectives

To generate dose-response data from human clinical studies and develop correlative dose-response data from relevant animal surrogates. The FDA seeks to support research to complement completed, ongoing, and planned controlled clinical infection studies, such as those supported by NIH, EPA, or DOD, for the purpose of providing data on the dose-response

relationship in humans ingesting food borne pathogenic microorganisms.

Research would be conducted to expand clinical studies to include additional strains and/or lower-dose levels to facilitate dose-response modeling. It may also include collection and use of subject samples (e.g., stools, peripheral blood) in the development of in vitro or ex vivo correlates (biomarkers) of human susceptibility, and/or expansion of clinical studies to collect data on food matrix effects.

In addition, the research must include the development of correlative dose-response data from relevant animal surrogates using the same bacterial strains, prepared under the same conditions, as used in the human dosing experiments, utilizing an appropriate dose range to allow extrapolation to low doses. Oral dose-response in animals will be required. Research may include both normal animals and immunocompromised animals. Applicable models of compromised host subpopulations include, but are not limited to, animals with defined defects of the innate or acquired immune system or with disruption of the composition and/or diversity of the indigenous gut microflora.

B. Protection of Human Research Subjects

Some activities carried out by a recipient under this announcement may be governed by the Department of Health and Human Services' (DHHS) regulations for the protection of human research subjects (45 CFR part 46). These regulations require recipients to establish procedures for the protection of subjects involved in any research activities. Prior to funding and upon request of the Office for Protection from Research Risks (OPRR), prospective recipients must have on file with OPRR an assurance to comply with 45 CFR part 46. This assurance to comply is called an Assurance document. It includes the designated Institutional Review Board for review and approval of procedures for carrying out any research activities occurring in conjunction with this award. If an applicable Assurance document for the applicant is not already on file with OPRR, a formal request for the required Assurance will be issued by OPRR at an appropriate point in the review process, prior to award, and examples of required materials will be supplied at that time. No applicant or performance site, without an approved and applicable Assurance on file with OPRR, may spend funds on human subject activities or accrue subjects. No performance site, even with an OPRR-

approved and applicable Assurance, may proceed without approval by OPRR of an applicable Assurance for the recipients. Applicants may wish to contact OPRR by facsimile (301-402-0527) to obtain preliminary guidance on human subjects issues. When contact OPRR, applicants should provide their institutional affiliation, geographic location, and all available request for application (RFA) citation information.

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 may be grounds for suspension or termination of the agreement. Progress reports will be required quarterly within 30 days following each Federal fiscal quarter (January 31, April 30, July 30, October 31), except that the fourth report which will serve as the annual report and will be due 90 days after the budget expiration date. CFSAN 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 the PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued 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 are not eligible to receive awards.

Members of the Food Safety Initiative Risk Assessment Consortium and/or their collaborators are *not* eligible to compete for these program funds.

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/or (2) the availability of Federal FY funds.

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 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.

FDA scientists will collaborate with the recipient and have final approval on the experimental protocol. This collaboration may include protocol design, data analysis, interpretation of findings, co-authorship of publications, and the development and filing of patents.

VI. Review Procedure and Criteria

A. Review Method

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. 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. Final funding decisions will be made by the Commissioner of Food and Drugs or his designee.

B. Program Priorities and Review Criteria

Funding priority will be for research proposals that will provide data for dose-response models for the following foodborne pathogens: Shiga-like toxin-producing *Cryptosporidium parvum*, pathogenic *Escherichia coli*, *Listeria monocytogenes*, Norwalk virus, *Salmonella* spp., *Shigella* spp., *Vibrio* spp., and *Staphylococcus* spp. enterotoxin. Other foodborne pathogens will also be considered. As previously stated, proposed research must be conducted in collaboration with completed, ongoing, or planned human clinical trials.

All comments received on the funding priority will be taken into consideration and will receive a response.

All applications will be evaluated by program and grants management staff for responsiveness. Applications determined not to be within the scope of the project objectives will be considered nonresponsive. Applications considered nonresponsive will be returned to the applicant, without being reviewed. Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their application. All questions of a technical or scientific nature must be directed to the CFSAN program staff and all questions of an administrative or financial nature must be directed to the grants management staff (address above). Applications will be based on the following criteria:

1. Research should be proposed on dose-response that is within the objectives listed in Research Goals and Objectives, section II of this document.
2. Whether the proposed study is within the budget and costs have been adequately justified and fully documented;
3. Soundness of the rationale for the proposed study and appropriateness of the study design to address the objectives of RFA;
4. Availability and adequacy of laboratory and associated animal facilities;
5. Availability and adequacy of support services, e.g., biostatistical computer, data bases, etc., and;
6. Research experience, training, and competence of the principal investigator and support staff.

VII. Submission Requirements

The original and five copies of the completed Grant Application Form PHS 398 (Rev. 5/95) or the original and two copies of the PHS 5161 (Rev. 7/92) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Robert L. Robins (address above). State and local governments may choose to use the PHS 398 application form in lieu of the PHS 5161. The application receipt date is June 18, 1998. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it 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-CFSAN-98-1."

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during 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), NIH. Any application that is sent to NIH, that is then forwarded to FDA and not received in time for orderly processing, will be deemed unresponsive and returned to the applicant. Instructions for completing the application forms can be found on the NIH home page on the Internet (address: <http://www.nih.gov/grants/funding/phs398/phs398.html>; the forms can be found at http://www.nih.gov/grants/funding/phs398/forms_toc.html). However, as noted previously, applications are not to be mailed to NIH. Applications must be submitted via mail delivery as stated previously. FDA is unable to receive applications via Internet.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/95). 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. Applicants are also advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH on its applications. Do not send applications to CSR, NIH. Applications from State and local governments may be submitted on Form PHS 5161 (Rev. 7/92) or Form PHS 398 (Rev. 5/95).

The face page of the application should reflect RFA's number RFA-FDA-CFSAN-98-1.

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 FOIA as amended (5 U.S.C. 552), as determined by the freedom of information officials of DHHS 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 and/or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated: April 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-11743 Filed 5-1-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96P-0090]

Determination That Testosterone Propionate 2% Ointment Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending a previous determination regarding the fact that testosterone propionate 2% ointment (Perandren Ointment) was not withdrawn from sale for reasons of safety or effectiveness. FDA has determined that it is not appropriate at this time to accept abbreviated new drug applications (ANDA's) for testosterone propionate 2% ointment.

FOR FURTHER INFORMATION CONTACT:

David T. Read, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION: ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as a "listed drug." A listed drug is one that has an effective approval, either under section 505(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(c)) for safety and effectiveness or under section 505(j) of the act, which has not been withdrawn for reasons of safety or effectiveness (21 CFR 314.3, see also 21 U.S.C. 355(j)(6)). Neither at the time of ANDA submission nor at the time of ANDA approval is it essential that a listed drug be currently marketed.

FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (popularly referred to as the "Orange Book") contains the official register of listed drugs, and a drug is removed from this register in either of two ways. First, a listed drug is removed if the agency withdraws or suspends approval of the drug's new drug application (NDA) or ANDA for reasons of safety or effectiveness. Second, in the case of a listed drug that was discontinued from sale but did not have its approval withdrawn or had its approval withdrawn for reasons other than safety or effectiveness, the drug is removed if FDA determines that it was discontinued from sale for reasons of