

### C. Deadlines

1. Applications shall be considered as meeting a deadline if they are either:

A. Received at the above address on or before the deadline date, or

B. Sent on or before the deadline date to the above address, and are received in time for the review process.

Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailings.

2. Applications that do not meet the criteria above are considered late applications and will be returned to the applicant.

### Where to Obtain Additional Information

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement 610. You will receive a complete program description, information on application procedures, and application forms. The announcement is also available through the CDC homepage on the Internet. The address for the CDC homepage is [http://www.cdc.gov]. CDC will not send application kits by facsimile or express mail.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-13, Atlanta, GA 30305, telephone (404) 842-6796.

Programmatic technical assistance may be obtained from Ted Jones, Project Officer, Office of Research Grants, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), Mailstop K-58, 4770 Buford Highway, NE., Atlanta, GA 30341-3724, telephone (770) 488-4824.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Information is included on a separate sheet with the application kit for obtaining copies of: "Injury Control in the 1990s: A National Plan for Action,"

(Atlanta: Centers for Disease Control and Prevention, 1993); "Injury In America" (National Academy Press, 2101 Constitution Avenue, NW, Washington, DC 20418—ISBN0-309-03545-7); "Injury Prevention: Meeting the Challenge" (supplement to the American Journal of Preventive Medicine, (Vol. 5, no. 3, 1989)); "Cost of Injury" (Dorothy P. Rice, Ellen J. MacKenzie, and Associates), "Cost of Injury: A Report to the Congress" (San Francisco, California: Institute for Health and Aging, University of California and Injury Prevention Research Center, The Johns Hopkins University, 1989); "A Framework for Assessing the Effectiveness of Disease and Injury Prevention," (CDC, "Morbidity and Mortality Weekly Report," March 27, 1992, Volume 41, Number RR-3, pages 5-11) and "Assessing the Effectiveness of Disease and Injury Prevention Programs: Costs and Consequences" (CDC, "Morbidity and Mortality Weekly Report," August 18, 1995, Volume 44, Number RR10).

Dated: January 11, 1996.

Joseph R. Carter,

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

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### [Announcement Number 611]

### Grants for Violence-Related Injury Prevention Research Notice of Availability of Funds for Fiscal Year 1996

#### Introduction

The Centers for Disease Control and Prevention (CDC) announces applications are being accepted for Violence-Related Injury Prevention Research Grants for fiscal year (FY) 1996. The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Violent and Abusive Behavior (To order a copy of "Healthy People 2000," see the Section "Where to Obtain Additional Information.")

#### Authority

This program is authorized under Sections 301, 391, 393, and 394 of the Public Health Service Act (42 U.S.C. 241, 280b, 280b-1a and 280-b-3). Program regulations are set forth in Title 42 CFR, Part 52.

### Eligible Applicants

Eligible applicants include all non-profit and for-profit organizations. Thus State and local health departments, State and local governmental agencies, universities, colleges, research institutions, and other public and private organizations, including small, minority and/or woman-owned businesses are eligible for these research grants. Current holders of CDC injury control research projects are eligible to apply.

### Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, child care, health care, and early childhood development services are provided to children.

### Availability of Funds

Approximately \$1.2 million is expected to be available for injury research grants in the areas of suicidal behavior, assaultive behavior among youth, and family and intimate violence. The specific program priorities for these funding opportunities are outlined with examples in this announcement under the section, "Programmatic Priorities." It is expected that the awards will begin on or about September 1, 1996, and will be made for a 12-month budget period within the appropriate (see below) project period. Funding estimates may vary and are subject to change.

For research projects targeted at areas of suicidal behavior and assaultive behavior among youth, approximately \$500,000 is available to fund 2-3 grants. Each grant will be supported for a maximum project period of three years at \$250,000 per year (including both direct and indirect costs).

For research projects targeted on family and intimate violence, approximately \$500,000 is available to fund 2-3 grants. Each grant will be supported for a maximum project period of three years at \$250,000 per year (including both direct and indirect costs). In addition, \$200,000 (including both direct and indirect costs) is available for one research project for population-based research to define the occurrence of injury and disability among women as a result of violence by their intimate partner. Awards will be made for a 12-month budget period within a project period not to exceed three years.

Grant applications that exceed the \$250,000 or \$200,000 per year caps will be returned to the investigator as non-responsive. Special consideration may be given to grant applicants who request smaller amounts of funding for project periods of one or two years duration. Continuation awards within the project period will be made on the basis of satisfactory progress demonstrated by investigators at work-in-progress monitoring workshops, the achievement of workplan milestones reflected in the continuation application, and the availability of Federal funds. In addition, continuation awards will be eligible for increased funding to offset inflationary costs depending upon the availability of funds.

Note: Grant funds will not be made available to support the provision of direct care services.

Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement) as necessary to meet the requirements of the program and strengthen the overall application.

#### Purpose

The purposes of this program are to:

A. Build the scientific base for the prevention of injuries and deaths due to violence in the following three priority areas: suicidal behavior, assaultive behavior among youth, and intimate partner violence as delineated in "Injury Control in the 1990s: A National Plan for Action," (Atlanta: Centers for Disease Control and Prevention, 1993) and "Healthy People 2000."

B. Identify effective strategies to prevent violence-related injuries.

C. Expand the development and evaluation of current and new intervention methods and strategies for the primary prevention of violence-related injuries.

D. Encourage professionals from a wide spectrum of disciplines such as medicine, health care, public health, criminal justice, and behavioral and social sciences, to undertake research to prevent and control injuries from assaultive youth behavior, family and intimate violence, and suicidal behavior.

E. Encourage the training of pre-doctoral minority investigators to work in the area of violence research.

#### Program Requirements

The following are applicant requirements:

A. A principal investigator who has conducted research, published the findings, and has specific authority and responsibility to carry out the proposed project.

B. Demonstrated experience in conducting, evaluating, and publishing injury control research on the applicant's project team.

C. Effective and well-defined working relationships within the performing organization and with outside entities which will ensure implementation of the proposed activities.

D. The ability to carry out injury control research projects.

E. The overall match between the applicant's proposed theme and research objectives, and the program priorities as described under the heading, Programmatic Priorities.

#### Programmatic Priorities

Grant applicants should concentrate on the need to reduce morbidity, mortality, and disabilities caused by suicidal behavior, assaultive behavior among youth, and family and intimate partner violence.

Applicants are encouraged to propose research that (1) enhances our understanding of social, economic, and environmental factors that may affect the frequency and severity of suicidal and assaultive behavior among youth; and (2) evaluates policies, programs, or interventions that may reduce suicidal and assaultive behavior among youth via the modification of social, economic, and environmental factors.

Applicants are also encouraged to propose research that (1) addresses and defines the needs of mothers and children in families where intimate partner violence occurs, and (2) utilizes population-based research that focuses on the occurrence of injury and disability among women as a result of intimate partner violence.

Examples of possible projects listed under the priority areas below are by no means exhaustive. Innovative alternative approaches are encouraged.

#### *Injury From Suicidal and Assaultive Behavior*

(1) *Enhancing our understanding of social, economic, and environmental factors that may affect suicidal behavior:*

- Study how choice of method (firearm, overdosing, etc.) in planning or attempting suicidal behavior is influenced by cultural, social, or environmental factors.

- Conduct research to determine the nature of suicide risk among gay and lesbian persons in comparison to the general population.

- Evaluate policies, programs, or interventions that may reduce suicidal behavior via the modification of social, economic, or environmental circumstances.

- Assess the effectiveness of interventions that attempt to remove access to lethal means in reducing injury and severity of injury from suicidal behavior.

(2) *Enhancing our understanding of the importance of social and economic factors that influence assaultive behavior among youth:*

- Study why many socioeconomically disadvantaged youth do not engage in assaultive behavior despite their socioeconomic status.

- Undertake research to increase our understanding of relationships between poverty and assaultive behavior among youth.

- Study how unequal access to criminal justice, health care, and educational systems is related to assaultive behavior.

- Evaluate policies, programs, or interventions that may reduce assaultive behavior among youth via the modification of social or economic circumstances.

#### *Family and Intimate Violence Prevention*

(1) *Address and define the needs of mothers and children in families where intimate violence occurs.*

- Undertake research to determine effective interventions for mothers and children in families with ongoing violence.

- Conduct studies to determine which mothers and children are most likely to be helped by interventions designed for families with ongoing violence.

- Examine variables related to mothers, children, and families that may predict intervention effectiveness.

- Conduct studies related to the impact of children witnessing violence in their families.

(2) *Define the incidence or prevalence of functional limitations and disabilities among women as a result of intimate partner violence.*

- Quantify injuries sustained (nature and severity) and subsequent short and long-term (1-year) functional limitations and disability.

- Quantify the use of acute care, mental health, rehabilitation, and social services.

- Identify risk factors for adverse outcomes.

Also of interest is research that more accurately defines the cost of violent injuries and the cost effectiveness or prevention effectiveness of interventions. Cost analysis should be included in the plans, where appropriate, to evaluate an intervention(s) that addresses one of the three priority areas of violence-related

injury research previously outlined, (i.e., suicidal behavior, assaultive behavior among youth, and family and intimate violence). A more complete discussion of methodologies for assessing cost analysis is presented in "A Framework for Assessing the Effectiveness of Disease and Injury Prevention," (CDC, "Morbidity and Mortality Weekly Report," March 27, 1992, Volume 41, Number RR-3, pages 5-11). (To receive information on these reports see the section Where to Obtain Additional Information.)

#### Evaluation Criteria

Upon receipt, applications will be screened by CDC staff for completeness and responsiveness as outlined under the previous heading, Program Requirements (A-E). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. Applications which are complete and responsive may be subjected to a preliminary evaluation by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant further review (triage); the CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process. Awards will be made based on priority score ranking by the Injury Research Grants Review Committee (IRGRC), programmatic priorities and needs by the Advisory Committee for Injury Prevention and Control, and the availability of funds.

A. The first review following the preliminary review will be a peer review to be conducted on all applications. Factors to be considered will include:

1. The specific aims of the research project, i.e., the broad long-term objectives, the intended accomplishment of the specific research proposal, and the hypothesis to be tested.

2. The background of the proposal, i.e., the basis for the present proposal, the critical evaluation of existing knowledge, and specific identification of the injury control knowledge gaps which the proposal is intended to fill.

3. The significance and originality from a scientific or technical standpoint of the specific aims of the proposed research, including the adequacy of the theoretical and conceptual framework for the research.

4. For competitive renewal applications, the progress made during the prior project period. For new applications, (optional) the progress of preliminary studies pertinent to the application.

5. The adequacy of the proposed research design, approaches, and methodology to carry out the research, including quality assurance procedures, plan for data management, statistical analysis plan, and plans for inclusion of minorities and both sexes.

6. The extent to which the evaluation plan will allow for the measurement of progress toward the achievement of the stated objectives.

7. Qualifications, adequacy, and appropriateness of personnel to accomplish the proposed activities, including pre-doctoral minority investigator(s).

8. The degree of commitment and cooperation of other interested parties (as evidenced by letters detailing the nature and extent of the involvement).

9. The reasonableness of the proposed budget to the proposed research and demonstration program.

10. Adequacy of existing and proposed facilities and resources.

11. An explanation of how the research findings will lead to feasible, cost-effective injury interventions.

B. The second review will be conducted by the Advisory Committee for Injury Prevention and Control. The factors to be considered will include:

1. The results of the peer review.
2. The significance of the proposed activities in relation to the objectives outlined under the section, Programmatic Priorities.
3. National needs.
4. Overall distribution among:
  - The three priority areas of violence-related injury research: suicidal behavior, assaultive behavior among youth, and family and intimate violence;
  - The major disciplines of violence-related injury prevention: social and behavioral science, biomechanics, and epidemiology;
  - Populations addressed (e.g., adolescents, racial and ethnic minorities, the elderly, children, urban, rural).
5. Budgetary considerations (e.g., preference may be given to applicants who submit proposals requesting funding for research projects of one to two years duration).
6. Additional consideration will be given to those applicants who provide evidence of an injury research training program for pre-doctoral minority investigators.

C. Continued Funding: Continuation awards made after FY 1996, but within

the project period, will be made on the basis of the availability of funds and the following criteria:

1. The accomplishments reflected in the progress report of the continuation application indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual workplan and satisfactory progress has been demonstrated through monitoring presentations or work-in-progress workshops;

2. The objectives for the new budget period are realistic, specific, and measurable;

3. The methods described will clearly lead to achievement of these objectives;

4. The evaluation plan will allow management to monitor whether the methods are effective; and

5. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds.

#### Executive Order 12372 Review

Applications are not subject to the review requirements of Executive Order 12372 review.

#### Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirements.

#### Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.136.

#### Other Requirements

##### *Human Subjects*

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

##### *Animal Subjects*

If the proposed project involves research on animal subjects, the applicant must comply with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions." An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the

Office of Protection from Research Risks at the National Institutes of Health.

#### *Women and Minority Inclusion Policy*

It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947-47951.

#### *Application Submission and Deadlines*

##### A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Specialist (whose address is reflected in section B, "Applications"). It should be postmarked no later than one month prior to the planned submission deadline, (e.g., February 14 for March 14 submission). The letter should identify the announcement number, name the principal investigator, and specify the priority area of violence-related injury research (i.e., suicidal behavior, assaultive behavior among youth, and family and intimate violence) addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

##### B. Applications

Applicants should use Form PHS-398 (OMB No. 0925-0001 Revised 5/95) and adhere to the ERRATA Instruction Sheet for Form PHS-398 contained in the

Grant Application Kit. Please submit an original and five copies, on or before March 14, 1996, to: Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305.

##### C. Deadlines

1. Applications shall be considered as meeting a deadline if they are either:

A. Received at the above address on or before the deadline date, or  
B. Sent on or before the deadline date to the above address, and received in time for the review process. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailings.

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Programmatic technical assistance may be obtained from Ted Jones, Project Officer, Extramural Research Grants Branch, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), Mailstop K-58, 4770 Buford Highway, NE., Atlanta, GA 30341-3724, telephone (404) 488-4824.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary

Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Copies of "Injury Control in the 1990s: A National Plan for Action," (Atlanta: Centers for Disease Control and Prevention, 1993) and "A Framework for Assessing the Effectiveness of Disease and Injury Prevention," (CDC, "Morbidity and Mortality Weekly Report," March 27, 1992, Volume 41, Number RR-3, pages 5-11) may be obtained by calling (404) 488-4265.

Information for obtaining the suggested readings, "Violence and the Public's Health," "Understanding and Preventing Violence," and "Violence in America: A Public Health Approach," is included on a separate sheet with the application kit.

Dated: January 11, 1996.

Joseph R. Carter,

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 96-566 Filed 1-18-96; 8:45 am]

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## Food and Drug Administration

[Docket No. 95N-0407]

### Animal Drug Export; Denagard® (Tiamulin) Injection

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Fermenta Animal Health Co. has filed an application requesting approval for the export of the animal drug Denagard® (tiamulin) injection for swine to Canada.

**ADDRESSES:** Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of food animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

**SUPPLEMENTARY INFORMATION:** The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act