

of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/ New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Antimicrobial Resistance

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food Producing Animals with Respect to Antimicrobial Resistance" (VICH GL27) should be made available for public comment. However, subsequent to the June 2001 Steering Committee meeting, the FDA decided to delay the publication of the draft VICH guidance in the United States until the FDA draft guidance (#152) related to antimicrobial resistance was published. FDA believed that it was important to first develop its thinking on how data, such as that described in the draft VICH guidance, could be used for completing an assessment on antimicrobial resistance.

The draft VICH guidance is an initial step in developing harmonized technical guidance in the European Union, Japan, and the United States for approval of therapeutic antimicrobial

veterinary medicinal products intended for use in food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern.

This draft guidance outlines the types of studies and data that may be used to characterize the potential for resistance to develop in the target animal when an antimicrobial drug product is used under the proposed conditions. This includes information which describes the drug substance, drug product, nature of the resistance, and potential exposure of gut flora in the target animal species.

FDA and the VICH Expert Working Group on Antimicrobial Resistance will consider comments about the draft guidance document. Information collection is covered under the Office of Management and Budget control number 0910-0032.

III. Significance of Guidance

This draft document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." Because guidance documents are not binding, mandatory words such as "must," "shall," and "will" in the original VICH document have been substituted with "should." Similarly, words such as "require" or "requirement" have been replaced by "recommend" or "recommendation" as appropriate to the context.

The draft VICH guidance (#144) is consistent with the agency's current thinking, described in draft guidance #152, on the type of preapproval information that should be considered for new veterinary medicinal products for food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document to the Dockets Management Branch (see ADDRESSES). Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Two copies of any mailed comments are to be submitted, except

that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may also be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select Docket No. 03D-0051 "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance" and follow the directions.

Copies of the draft guidance document entitled "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance" (VICH GL27) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: June 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA-03-019 Fiscal Year 2003 Geriatric Academic Career Awards (GACA)—CFDA 93.250

AGENCY: Health Resources and Services Administration.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the second of two solicitations for the Geriatric Academic Career Awards Program for Fiscal Year 2003.

Purpose: The purpose of this program is to increase the number of junior faculty in geriatrics at accredited schools of medicine and osteopathic medicine and to promote their careers as academic geriatricians. The GACA stipend supports the career development of junior faculty members for a period of five years.

Authorizing Legislation: These applications are solicited under the

authority of Title VII, section 753 (c), of the Public Health Service Act (PHS), (42 U.S.C. 294c).

Eligible Applicants: Geriatric Academic Career Awards are provided for individuals who meet the following criteria: (1) Are board certified or board eligible in internal medicine, family practice, or psychiatry; (2) have completed an approved fellowship program in geriatrics; and (3) have a junior faculty appointment at an accredited school of medicine (allopathic or osteopathic).

Funding Priorities and/or Preferences: None.

Service Requirements: Award recipients agree to serve as members of the faculties of accredited schools of allopathic or osteopathic medicine providing teaching services, within the service requirements under this award, for up to 5 years. Prior to submitting an application for the Geriatric Academic Career Award, individuals must have an agreement with an eligible school setting forth the terms and conditions of the award. The agreement with the school must permit the individual to serve as a full-time (as determined by the school) member of the faculty, for not less than the period of the award. As provided in section 753 (c)(5), an individual who receives an award shall provide training in clinical geriatrics, including the training of interdisciplinary teams of health care professionals. The provision of such training shall constitute at least 75 percent of the obligations of the individual under this award. Geriatric career awards are made directly to individuals, not institutions.

Review Criteria

(1) Extent to which the applicant's career goals as identified in the career development plan meet the purpose of the Geriatric Academic Career Award—to develop into an academic geriatrician who emphasizes teaching geriatrics, including teaching interdisciplinary teams—and the quality of the applicant's plan for assessing his or her own progress toward meeting career goals; (Maximum Value: 20 points)

(2) Potential of the applicant to achieve identified goals and objectives based on past training and experience; (Maximum: 20 points)

(3) Extent to which specific plans will result in (a) meeting the statutory service requirement (75% time pursuing the goals of the GACA), (b) interacting with and learning from other clinician-educators locally and nationally, and (c) obtaining the necessary pedagogical skills to achieve career goals; (Maximum Value: 20 points)

(4) Extent to which specific plans will result in research and/or publication opportunities and productivity in national professional societies; (Maximum Value: 20 points)

(5) Extent to which the commitment of the mentor and institution to provide a supportive environment for the achievement of the applicant's career goals and willingness to meet reporting requirements are demonstrated. (Maximum Value: 20 points)

Estimated Amount of Available Funds: It is estimated that \$1 million will be available for this second solicitation in fiscal year 2003.

Estimated Number of Awards: The estimated number of awards will be 20.

Estimated or Average Size of Each Award: The estimated size of each award will be \$55,000.

Estimated Project Period: Applications may be submitted for a five-year grant period. The first budget period is September 1, 2003–August 31, 2004; the second budget period is September 1, 2004–September 29, 2005; the third budget period is September 30, 2005–September 29, 2006; the fourth budget period is September 30, 2005–September 29, 2006; the fifth budget period is September 30, 2006–September 29, 2007.

Application Requests, Availability, Dates and Addresses: Application materials are available for downloading via the Web at <http://bhpr.hrsa.gov/grants.htm>. In order to be considered for competition, applications must be postmarked or delivered by July 14, 2003, to the HRSA's Grants Management Office ATTN: GACA, 5600 Fishers Lane, Room 11A–33, Rockville, MD 20857. Applicants should request a legibly dated U.S. Postal postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered Postmarks shall not be acceptable as proof of timely mailing. Applications submitted after the deadline date will be returned to the applicant and not processed. Applicants should note that HRSA anticipates accepting grant applications online in the last quarter of the Fiscal Year (July through September). Please refer to the HRSA grants schedule at <http://www.hrsa.gov/grants.htm> for more information.

Projected Award Date: September 30, 2003.

For Further Information Contact: Kathleen Bond, Division of State, Community and Public Health, Bureau of Health Professions, HRSA, Room 8–103, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone number: (301) 443–8681. E-mail: kbond@hrsa.gov.

Paperwork Reduction Act

The Application for the Geriatric Academic Career Awards Program has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0915–0060. The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Dated: May 29, 2003.

Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

North American Wetlands Conservation Council (Council) Meeting Announcement

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The Council will meet to select North American Wetlands Conservation Act (NAWCA) grant proposals for recommendation to the Migratory Bird Conservation Commission (Commission). The meeting is open to the public.

DATES: July 9, 2003, 1 p.m.

ADDRESSES: The meeting will be held at the Hotel Loews Le Concorde, 1225 Place Montcalm, Quebec City, Quebec, Canada. The Council Coordinator is located at U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Mail Stop: MBSP 4501–4075, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: David A. Smith, Council Coordinator, (703) 358–1784 or dbhc@fws.gov.

SUPPLEMENTARY INFORMATION: In accordance with NAWCA (Pub. L. 101–233, 103 Stat. 1968, December 13, 1989, as amended), the State-private-Federal Council meets to consider wetland acquisition, restoration, enhancement and management projects for recommendation to, and final funding approval by, the Commission. Proposal due dates, application instructions, and eligibility requirements are available through the NAWCA Web site at <http://birdhabitat.fws.gov>. Proposals require a minimum of 50 percent non-Federal matching funds. Canadian, Mexican, U.S. Standard and U.S. Small grant proposals will be considered at the