

Board of Governors of the Federal Reserve System, December 3, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90-28843 Filed 12-7-90; 8:45 am]

BILLING CODE 6210-01-M

Saastopankkien Keshukus-Osake-Pankki; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 27, 1990.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President), 33 Liberty Street, New York, New York 10045:

1. *Saastopankkien Keshukus-Osake-Pankki*, Helsinki, Finland; to acquire Haskell Financing, Inc., Dallas, Texas,

and thereby engage in making, acquiring, and or servicing purchase money loans for industrial equipment purchase to § 225.23(b)(1); leasing personal property pursuant to § 225.25(b)(5) of the Board's Regulation Y.

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[FR Doc. 90-28844 Filed 12-7-90; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Development of Clinical Guidelines for AIDS and HIV Infection

The Agency for Health Care Policy and Research announces that it is establishing a panel of experts and health care consumers to develop clinical practice guidelines for AIDS and HIV infection and invites nominations of qualified individuals to serve as the chairperson(s) and as panel members.

Background

The Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) enacted on December 19, 1989, added a new title IX to the Public Health Service Act (the Act), which established the Agency for Health Care Policy and Research (AHCPR) to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services. The AHCPR is to achieve its goals through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing and delivery of health care services.

Section 911 of the Act established within the AHCPR the Office of the Forum for Quality and Effectiveness in Health Care (the Forum). Section 912 of the Act directs the Forum to arrange for the development and periodic review and updating of clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

Section 912 also requires that the guidelines be:

1. Based on the best available research and professional judgment;

2. Presented in formats appropriate for use by physicians, health care practitioners, providers, medical educators, medical review organizations, and consumers of health care; and

3. In forms appropriate for use in clinical practice, educational programs, and reviewing quality and appropriateness of medical care.

Panel Nominations

The panel of qualified experts and health care consumers that will develop the guidelines for AIDS and HIV infection will consist of a chairperson(s) and nine to fifteen members. To assist in identifying members for the panel, AHCPR is requesting recommendations from a broad range of interested individuals and organizations, including physicians representing specialty and general practices, nurses, and allied health and other health care practitioners, as well as consumers with pertinent experience or information. AHCPR is especially interested in receiving nominations of individuals with experience in developing guidelines for AIDS and HIV-related conditions, persons representing affected minority groups, women, and persons experienced in the care of children with AIDS and HIV infection.

This Notice requests nominations of qualified individuals to serve on the panel as members and as panel chairperson(s). The functions of the panel chairperson(s) are critical to the guideline development process and the final product. The chairperson(s) will provide leadership to the panel regarding methodology, literature review, panel deliberations, and formation of the final product. Nominations for the chairperson(s) should take into consideration the criteria specified below, which the AHCPR will use in making its selection.

AHCPR will appoint the panel chairperson(s) from among the nominations received using criteria that include the following:

- Relevant training and clinical experience
- Demonstrated interest in quality assurance and research on the clinical condition including publication of relevant peer-reviewed articles
- Commitment to the need to produce clinical guidelines
- Recognition in the field with a record of leadership in relevant activities
- Broad public health view of the utility of the particular procedure or clinical service

- Demonstrated capacity to lead a health care team in a group decisionmaking process
- Demonstrated capacity to respond to consumer concerns
- Prior experience in developing guidelines for the clinical conditions in question.

Once the panel chairperson(s) have been appointed, the nominations for members of the panel will be submitted for further review and consideration to the selected chairperson(s) who will in turn recommend proposed panel members to AHCPR. Appointments of the panel members will be made by the AHCPR, after review of proposed members' qualifications and the overall composition of the panel to ensure representation of a range of experience and expertise.

Nominations should indicate whether the individual is being recommended to serve as the panel chairperson(s) or to serve as a member of the panel. Each nomination must include a copy of the individual's curriculum vitae or resume, plus a statement of the rationale for the specific nomination. To be considered, nominations must be received by January 31, 1991 at the following address:

Office of the Forum on Quality and Effectiveness in Health Care,
Attention: Director, HIV Clinical Policy Program, Agency for Health Care Policy and Research, 5600 Fishers Lane, Parklawn Building, room 18A46, Rockville, MD 20857.

For Additional Information

Additional information on the guideline development process is contained in the AHCPR Program Note, Clinical Guideline Development dated August 1990. This Program Note, describing the activities underway by AHCPR for developing clinical practice guidelines, includes the process and criteria for selecting the panels. Copies may be obtained by calling the Center for Research Dissemination and Liaison, Agency for Health Care Policy and Research, at (301) 443-2904.

For further information on the process for developing guidelines for AIDS and HIV infection, contact Janet Arrowsmith-Lowe, M.D., Director, HIV Clinical Policy Program, Office of the Forum on Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, at the above address.

Dated: December 4, 1990.

J. Jarrett Clinton,
Assistant Surgeon General, Acting
Administrator.

[FR Doc. 90-28649 Filed 12-7-90; 8:45 am]

BILLING CODE 4160-17-M

Food and Drug Administration

[Docket No. 75P-0248]

Vitamin K Active Substances in Animal Feeds; Notice Concerning Food Additive Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a notice concerning the regulatory status of certain vitamin K active substances (VKAS) in animal food. The agency earlier concluded that certain VKAS are food additives but declined to formalize their regulatory status. This notice states that such VKAS are required to be marketed under provisions of a food additive regulation.

FOR FURTHER INFORMATION CONTACT: George Graber, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4438.

SUPPLEMENTARY INFORMATION: On July 13, 1990, the District Court of the United States for the Eastern District of New York issued an order requiring FDA to publish a notice under § 570.38 (21 CFR 570.38), providing for use of vitamin K active substances (VKAS) in accordance with one of the four alternatives listed in § 570.38(c). Section 570.38 is an FDA procedural regulation which determines the food additive status of a substance that is added to animal food. Section 570.38(b) provides that, if the agency concludes that the substance in question is not generally recognized as safe (GRAS) or otherwise exempt from the definition of a food additive in section 201(s) of the Food, Drug, and Cosmetic Act (the act), the agency will publish a notice thereof in the Federal Register. Section 570.38(c) states that the notice will provide for one of four alternatives that include: (1) Issuing a food additive regulation; (2) issuing an interim food additive regulation; (3) requiring discontinuation of the marketing of the substance; or (4) implementing a combination of the foregoing.

The District Court's decision resulted from a lawsuit filed by Heterochemical Corp. following publication by FDA of a notice concerning the regulatory status of VKAS. In the notice, published April

19, 1983 (48 FR 16748), the agency stated that it had concluded that none of the VKAS about which it had knowledge were GRAS, but that two VKAS—menadione and menadione sodium bisulfite complex (MSBC)—were prior-sanctioned for use in poultry feed at 2 to 4 grams per ton (g/ton). However, the agency concluded that it would not propose the issuance of food additive or GRAS affirmation regulations at that time. The agency decision not to formalize the regulatory status of the VKAS in question was based on its conclusion that VKAS had been added to animal food for more than 30 years without apparent animal or human safety problems. The agency's decision also reflected its assessment of its regulatory priorities and enforcement resources at that time. The agency advised those persons that intended to market new VKAS in the future to consult with it first in case the substance would raise potential safety questions such that a food additive regulation would be required.

The agency's 1983 notice responded to a petition filed by Heterochemical Corp., in which the firm asked the agency to review and clarify the legal status of several VKAS then being used as supplements in animal food. Heterochemical Corp. asked FDA to: (1) Require discontinuation of the use of menadione; (2) require discontinuation of the use of menadione sodium bisulfite; (3) declare that MSBC is GRAS for use solely in poultry feed at levels of up to 2 grams per ton; (4) require the discontinuation of use of MSBC for all other purposes; (5) and establish a reference standard for MSBC. See the Federal Register of August 18, 1976 (41 FR 35009).

FDA has concluded that it does not have in its possession enough scientific data and information to support publication of a food additive regulation for any of the VKAS in question. The agency has also concluded that publication of an interim food additive regulation for those VKAS would not be appropriate. Therefore, the agency is issuing this notice to state that the marketing of VKAS, other than menadione or MSBC for use in poultry feed at 2 to 4 g/ton is required to be done under provisions of a food additive regulation. Menadione dimethylpyrimidinol bisulfite may be marketed under the provision of 21 CFR 573.620. Persons who wish to market such substances should submit a food additive petition under the provisions in section 409 of the act. Such persons may also request GRAS affirmation under appropriate regulations.

The FDA has determined that it is not required to examine the economic impact of this notice in accordance with the Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). This notice is not a rule or regulation, but instead is a declaratory order under 5 U.S.C. 554(e) to terminate a controversy or remove uncertainty. Compare *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 624-25 (1973).

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 3, 1990.

Ronald G. Chesebrough,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-28848 Filed 12-7-90; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92-463, the Annual Report for the following Health Resources and Services Administration's Federal Advisory Committee has been filed with the Library of Congress:

Advisory Commission on Childhood Vaccines

Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading Room, Room 1026, Thomas Jefferson Building, Second Street and Independence Avenue, SE., Washington, DC, or weekdays between 9 a.m. and 4:30 p.m. at the Department of Health and Human Services, Department Law Library, HHS North Building, room G-619, 330 Independence Avenue, SW., Washington, DC, telephone (202) 245-6791. Copies may be obtained from: Ms. Rosemary Havill, Vaccine Injury Compensation Program, Bureau of Health Professions, room 702, 6001 Montrose Road, Rockville, Maryland 20852, Telephone (301) 443-6593.

Dated: December 4, 1990.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 90-28846 Filed 12-7-90; 8:45 am]

BILLING CODE 4160-15-M

Program Announcement for Cooperative Agreements for Acquired Immunodeficiency Syndrome (AIDS) Regional Education and Training Centers Program

The Health Resources and Services Administration (HRSA), announces that during fiscal year (FY) 1991 that \$16,907,000 is available to initiate and continue the development of AIDS Regional Education and Training Centers (ETCs) as authorized by section 788A of the Public Health Service Act (the Act). The continuation of multi-year projects approved in prior years is estimated to cost \$1,125,000.

Approximately \$15,782,000 is expected to be available for 16 competitive awards averaging \$986,375.

In the past, section 301 of the Act has also been used to implement the ETC training program. Applications will also be accepted under the authority of section 301 should funds become available.

The ETCs will provide multidisciplinary training for primary health care personnel in the care of people with Acquired Immunodeficiency Syndrome (AIDS) and other conditions related to infection with the Human Immunodeficiency Virus (HIV). Comments are invited on the proposed project requirements, funding preference, priorities and set-aside stated below.

Eligibility

Awards are made to accredited health professional schools and academic health science centers (see below):

1. To train the faculty of schools and graduate departments of medicine, nursing, osteopathic medicine, dentistry, public health, psychology, and allied health to teach health professions students to provide for the health care needs of individuals with HIV/AIDS;
2. With respect to improving clinical skills in the diagnosis, treatment and prevention of such syndrome, to educate and train the health professionals and clinical staff of schools of medicine, osteopathic medicine, and dentistry; and
3. To develop and disseminate curricula relating to the care and treatment of individuals with HIV/AIDS.

Accredited Health Professional Schools means schools of medicine, dentistry, osteopathic medicine, pharmacy, optometry, podiatric medicine, veterinary medicine, public health, and chiropractic, as defined in

section 701(4) of the Act, schools of allied health as defined in section 701(10) of the Act, and schools of nursing as defined in section 853 of the Act, which are located in States as defined in section 701(11) of the Act and which are accredited as provided in section 701(5) of the Act. The term also includes a "graduate program in health administration" and a "graduate program in clinical psychology" as defined in section 701(4) of the Act and a program for the training of physician assistants as defined in section 701(8)(A).

Academic Health Science Center means an organization within a post-secondary educational system, which brings together major divisions or programs of health professions instruction, research in the health sciences, and health services.

These definitions are consistent with the use of the terms within other title VII programs administered by HRSA.

Proposed Project Requirements

The proposed project requirements are designed to direct Federal resources where the greatest needs exist. Each project must define a geographic region and identify the types of providers to be targeted for training within that region. Thus, the focus of FY 1991 will be on clinical education of primary care providers in high HIV/AIDS prevalence areas. Consistent with this emphasis is the requirement that a minimum of two-thirds of the Federal funds provided must be expended to provide education to primary care providers (i.e., physicians, nurses, dentists, physician assistants, nurse practitioners, and dental hygienists).

A needs assessment must be made to guide program implementation. This assessment must be based on current epidemiological data, as well as training and educational needs within the defined region. Established centers will have up to one year to conduct the needs assessment and make required adjustments. New centers will also have up to one year for start-up activities and to conduct an educational and training needs assessment. The assessment must include training needs associated with rural and other low incidence areas within the defined region.

Each ETC must provide or perform the following:

- Clinical training of primary care physicians, nurses, dentists, physician assistants, nurse practitioners, and dental hygienists;
- An updated needs-assessment of the education and training needs of the primary care providers within the proposed service area which is linked to the allocation of Federal funds;