

Status: Open to the public, limited only by the space available.

Purpose: The Committee advises and makes recommendations to the Secretary, the Assistant Secretary for Health, the Director, CDC, and Director, National Center for Injury Prevention and Control (NCIPC) regarding feasible goals for the prevention and control of injury. The Committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control. The Committee provides advice on the appropriate balance of intramural and extramural research, and also provides guidance on the needs, structure, progress and performance of intramural programs, and on extramural scientific program matters. The Committee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Committee also recommends areas of research to be supported by contracts and cooperative agreements and provides concept review of program proposals and announcements.

Matters to be Discussed: Following the Acting Director's update, which will include an introduction of the new NCIPC Director, NCIPC's Division of Violence Prevention will give an overview of violence against women programs. The Committee will also discuss reports from the November 28, 2000, meetings of the Subcommittee on Family and Intimate Violence Prevention and Subcommittee on Science and Program Review.

This notice is published less than 15 days prior to the meeting due to administrative delay.

Contact Person for More Information: Mr. Thomas E. Blakeney, Acting Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE, M/S K61, Atlanta, Georgia 30341-3724, telephone 770/488-1481.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 15, 2000.

Carolyn J. Russell,

*Management Analysis and Services Office,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Allergenic Products Advisory Committee, Biological Response Modifiers Advisory Committee, Blood Products Advisory Committee, Transmissible Spongiform Encephalopathies Advisory Committee, and the Vaccines and Related Biological Products Advisory Committee in the Center for Biologics Evaluation and Research (CBER). Nominations will be accepted for vacancies that will or may occur through January 31, 2002.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations and curricula vitae should be sent to the addresses below.

FOR FURTHER INFORMATION CONTACT: Regarding nominations, except for consumer representatives: Nancy T. Cherry, Scientific Advisors and Consultants Staff, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314.

Regarding nominations for consumer representatives: Maureen A. Hess, Office of Consumer Affairs (HFE-50), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301-827-4421.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of voting members with appropriate expertise for vacancies listed below.

1. *Allergenic Products Advisory Committee:* Three vacancies occurring August 31, 2001; immunology, pediatrics, internal medicine, biochemistry, statistics, and related scientific fields.

2. *Biological Response Modifiers Advisory Committee:* Five vacancies occurring March 31, 2001; biological response modifiers, immunology, virology, molecular biology, rDNA technology, infectious diseases, viral oncology, statistics, and cellular kinetics.

3. *Blood Products Advisory Committee:* Nine vacancies occurring September 30, 2001; clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, statistics, biological and physical sciences, and other related scientific fields.

4. *Transmissible Spongiform Encephalopathies Advisory Committee:* Three vacancies occurring January 31, 2002; clinical administrative medicine, hematology, virology, neurology, infectious diseases, immunology, blood banking, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, and other related professions.

5. *Vaccines and Related Biological Products Advisory Committee:* Three vacancies occurring January 31, 2002; immunology, molecular biology, rDNA, virology, bacteriology, epidemiology, biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.

Functions

Allergenic Products Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic diseases.

Biological Response Modifiers Advisory Committee

Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in

the prevention and treatment of a broad spectrum of human diseases.

Blood Products Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood and products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases.

Transmissible Spongiform Encephalopathies Advisory Committee

Reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health.

Vaccines and Related Biological Products Advisory Committee

Reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases.

Qualifications

Persons nominated for membership on the committees shall have adequately diversified experience appropriate to the work of the committee in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the committee. The particular needs at this time for each committee are shown above. The term of office is up to 4 years, depending on the appointment date.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees. Self-nominations are also accepted. Nominations shall include the name of the committee, a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member (name of committee(s) must be specified), and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or

contracts to permit evaluation of possible sources of conflict of interest.

Consumer Representatives

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees to represent consumer interests. Self-nominations are also accepted. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Selection of members representing consumer interests is conducted through procedures that include use of a consortium of consumer organizations that has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Nominations shall include a complete curriculum vitae of each nominee, current address and telephone numbers, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or in any advisory committee. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: November 7, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-29536 Filed 11-20-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0218]

Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol" dated October 2000. The guidance document provides information on the revised release limits to be used by the Center for Biologics Evaluation and Research (CBER) for its evaluation of standardized dust mite and grass allergen vaccines submitted to CBER for lot release. The establishment of suitable potency limits for standardized allergen vaccines submitted to CBER for lot release is necessary to help ensure the safety, purity, and potency of these products. The guidance document announced in this notice finalizes the draft guidance entitled "Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol" that was announced in the **Federal Register** on February 15, 2000.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of "Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol" dated November 2000 to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Joseph L. Okrasinski, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: