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]

BILLING CODE 4160–01–F

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:

I. Background

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'' November July 2000. The guidance document provides information to FDA reviewers regarding broader relative potency limits for CBER evaluation of standardized dust mite and grass allergen vaccines submitted to CBER for lot release. Issues addressed in the guidance document include, but are not limited to, the following: (1) Diagnostic equivalence, (2) theraputic equivalence, (3) safety equivalence, (4) lot-to-lot variation in allergen vaccine potency, and (5) current and broadened CBER release limits for standardized dust mite and grass allergen vaccines submitted to CBER for lot release. 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 (65 FR 7557).

This guidance document represents the agency's current thinking with regard to the potency limits for standardized dust mite and grass allergen vaccines. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: October 13, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29537 Filed 11–17–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–3010]

''Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' dated November 2000. The guidance document provides information on developing stability protocols for standardized grass pollen extracts. The development of suitable stability studies is necessary to determine the shelf life of standardized grass pollen extracts 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 Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' that was announced in the **Federal Register** of August 25, 1997.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' 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 guidance 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:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' dated November 2000. The guidance document is intended to provide information to manufacturers regarding stability studies on grass pollen extracts. Such stability studies are used to determine the shelf life of the product. This guidance document does not, however, change lot release criteria for these products. Issues addressed in the guidance document include, but are not limited to: (1) Current lot release criteria, (2) lot release versus stability protocol, (3) modified stability protocol, (4) retesting, (5) dealing with test failure, and (6) extension of dating. The guidance document announced in this notice finalizes the draft guidance entitled ''Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' that was announced in the **Federal Register** of August 25, 1997 (62 FR 44975).

This guidance document represents the agency's current thinking with regard to the testing limits in stability protocols for standardized grass pollen extract. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two