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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0218]

Draft "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 draft document entitled "Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol" dated January, 2000. The draft guidance document provides information on the revised release limits to be used by the Center for Biologics Evaluation and Research (CBER) for its evaluation of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 helps to ensure the safety, purity, and potency of these products.

DATES: Written comments may be submitted at any time, however, comments should be submitted by [*insert date 90 days after date of publication in the Federal Register*], to ensure their adequate consideration in preparation of the final document.

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 January, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

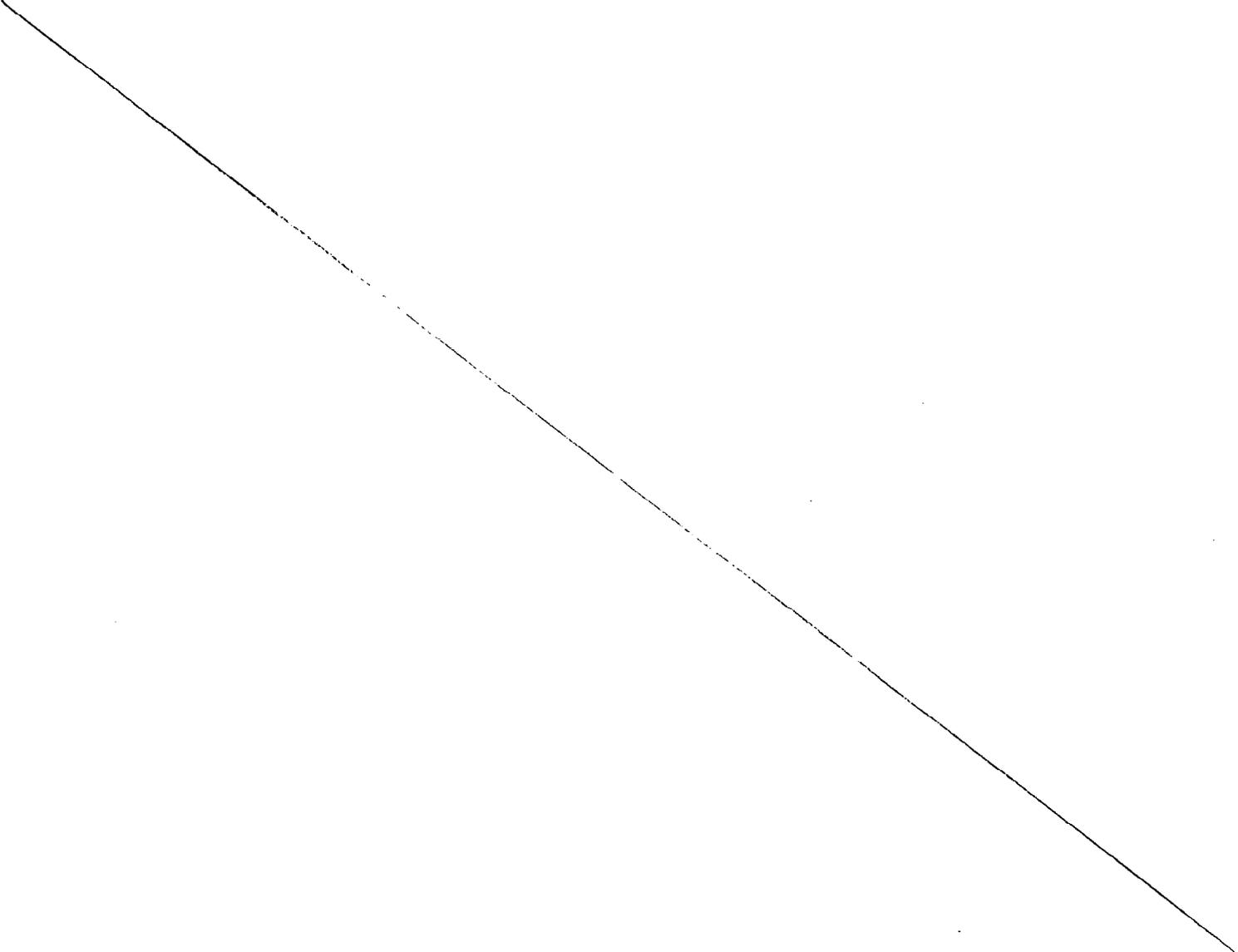
I. Background

FDA is announcing the availability of a draft document entitled “Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol” dated January, 2000. The draft guidance document, when finalized, would provide 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) therapeutic 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.

This draft 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 requirement of the applicable statute, regulations, or both. 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

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit Written comments at any time, however, comments should be submitted by [*insert date 90 days after date of publication in the **Federal Register***], to ensure adequate consideration in preparation of the final 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

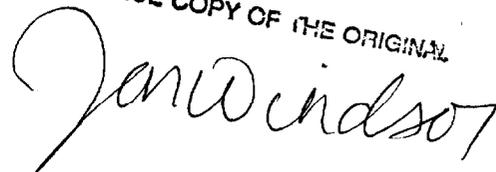
Persons with access to the Internet may obtain the document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 2/8/00
February 8, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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