

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-3010]

DMS

Display Date	11 19 00
Publication Date	11-20-00
Certifier	[Signature]

“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 The guidance document announced in this notice finalizes the draft guidance entitled “Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts” that was announced in the **Federal Register**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

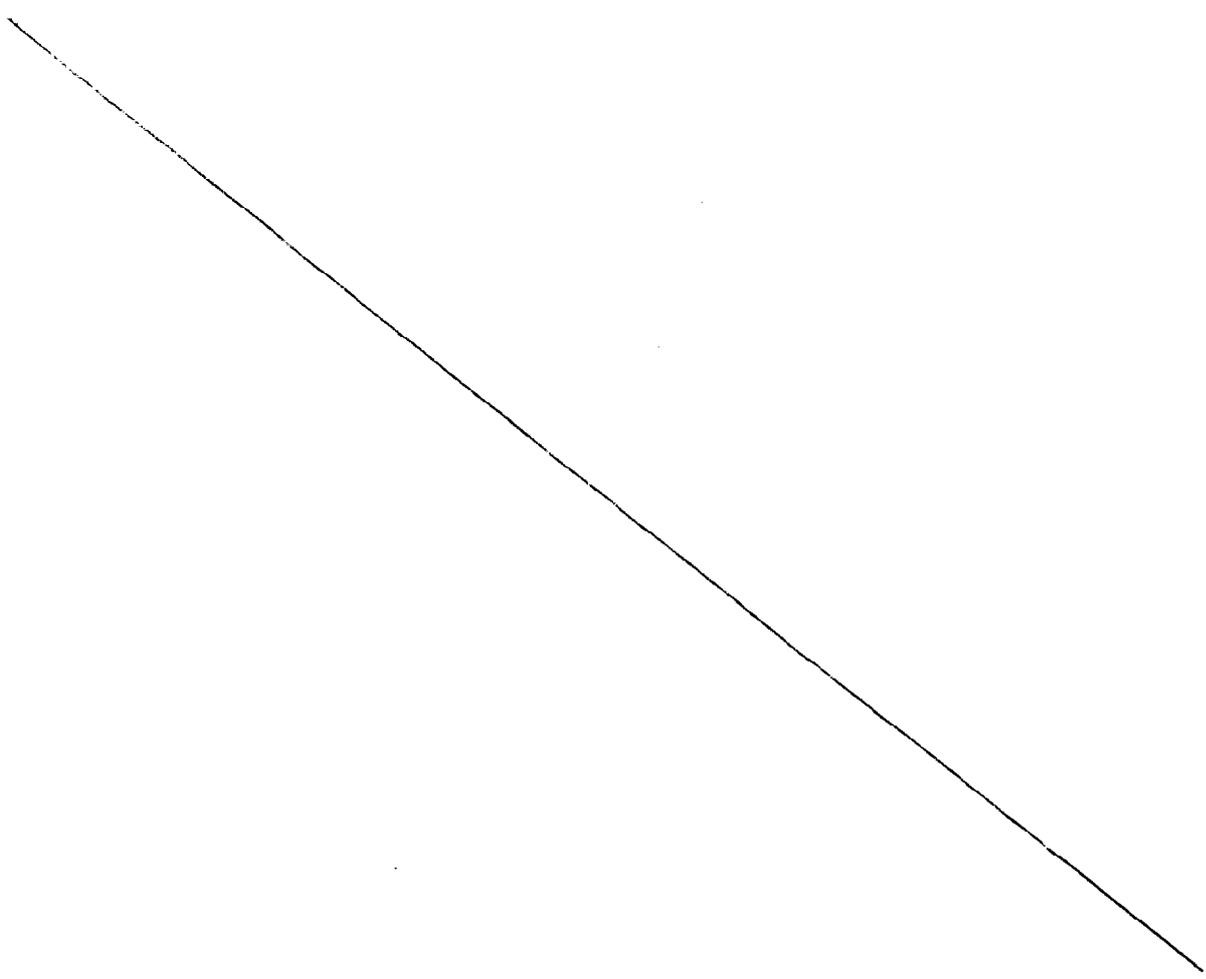
FDA is announcing the availability of a document entitled “Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts” dated November 2000. The guidance document is intended to provide information to manufacturers regarding stability studies on grass pollen extracts. 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

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

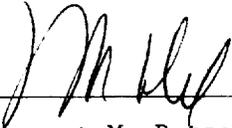
Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets 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: 11-6-00
November 6, 2000



Margaret M. Dotzel
Associate Commissioner for Policy

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

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
