DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Dissolution Testing of Immediate Release Solid Oral Dosage Forms'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5635.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Dissolution Testing of Immediate Release Solid Oral Dosage Forms.'' The purpose of this guidance document is to provide: (1) General recommendations for dissolution testing, (2) approaches for setting dissolution specifications related to biopharmaceutic characteristics of the drug substance, (3) statistical methods for comparing dissolution profiles, and (4) a process to help determine when dissolution testing is sufficient to grant a waiver for an in vivo bioequivalence study. Three categories of dissolution test specifications for immediate release drug products are described in the guidance: (1) Single-point specifications as routine quality control tests; (2) two-point specifications for characterizing the quality of the product and as a routine quality control test for certain types of drug products; and (3) dissolution profile comparison for accepting product sameness under scale-up and postapproval related changes (SUPAC), to waive bioequivalence requirements for lower strengths of a dosage form, and to support waivers of other bioequivalence requirements.

This document also provides recommendations for dissolution tests to help ensure continuous drug product quality and performance after certain postapproval manufacturing changes.

This guidance document represents the agency's current thinking on the dissolution testing of immediate release solid oral dosage forms. 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 statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this guidance is also available on the Internet at http://www.fda.gov/cder/guidance.htm.

Dated: August 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–22422 Filed 8–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–3010]

Draft Guidance for Industry on 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 draft guidance document entitled ''Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts (July 1997).'' This draft guidance document is intended to provide information to manufacturers regarding the development of stability studies to determine the shelf life of standardized grass pollen extracts to help ensure the safety, purity, and potency of these products.

DATES: Written comments may be submitted at any time, however, to ensure comments are considered for the next revision they should be submitted by October 24, 1997.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts (July 1997)'' to the Center for Biologics Evaluation and Research, Food and Drug Administration, Office of Communication, Training, and Manufacturers Assistance (HFM–40), 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request. The draft guidance 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.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts (July 1997).'' The draft guidance document provides a discussion of issues that should be considered in the development of stability protocols for allergenic extracts derived from grass pollen for diagnostic and immunotherapeutic uses.

The draft guidance document is intended to provide information to manufacturers regarding stability studies on grass pollen extracts. Such stability studies are used to empirically determine the shelf life of the product. This draft guidance document does not, however, change lot release criteria for these products. Issues addressed in the draft 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.

As with other guidance documents, FDA does not intend this draft guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The draft guidance document is intended to provide information and does not set forth requirements. The methods and procedures presented in the draft guidance document are suggestions. FDA anticipates that sponsors and investigators may develop alternative methods and procedures and discuss them with FDA. FDA may find those alternative methods and procedures acceptable. FDA recognizes that

advances will continue in the area of allergenic extracts and that this document may become outdated as those advances occur. This draft guidance document represents the agency's current thinking on testing limits in stability protocols for standardized grass pollen extracts. 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 statute, regulations, or both.

Interested persons may submit written comments on the draft guidance document to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday. Comments received will be considered in determining whether further revision of the draft guidance document is warranted.

Persons with access to the INTERNET may obtain the draft guidance document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: August 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–22421 Filed 8–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Listing of Members of the Food and Drug Administration's Senior Executive Service Performance Review Board

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces the persons who will serve on the FDA Performance Review Board (PRB). This action is being taken in accordance with Title 5 U.S.C. 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals, and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Arlene S. Karr, Office of Human Resources and Management Services (HFA–408), Food and Drug Administration, 5600 Fishers Lane, rm. 7B–32, Rockville, MD 20857, 301–827–4183.

The following persons will serve on the FDA PRB, which oversees the evaluation of performance appraisals of FDA's Senior Executive Service (SES) members:

Michael A. Friedman, M.D., Chairperson
Robert J. Byrd
Margaret J. Porter
Sharon Smith Holston
Mary K. Pendergast
William B. Schultz

Dated: August 14, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–22420 Filed 8–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA 1763, 2088 and R–142]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Request for Termination of Premium Hospital and/or Supplementary Medical Insurance and Supporting Regulations in 42 CFR 406.28 and 407.27; *Form No.:* HCFA–1763 (OMB No. 0938–0025); *Use:* The HCFA–1763 is used by beneficiaries to request voluntary termination from premium hospital and/or supplementary medical insurance. *Frequency:* One time only; *Affected Public:* Individuals or Households and Federal Government; *Number of Respondents:* 14,000; *Total Annual Responses:* 14,000; *Total Annual Hours:* 5,833.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Outpatient Rehabilitation Cost Report and Supporting Regulations in 42 CFR 413.20 and 413.24 *Form No.:* HCFA–2088 (OMB No. 0938–0037); *Use:* This form is used by Outpatient Rehabilitation Facilities to report their health care costs to determine the amount reimbursable for services furnished to Medicare beneficiaries. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 4,298; *Total Annual Responses:* 4,298; *Total Annual Hours:* 429,800.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Contained in BPD–393, Examination and Treatment for Emergency Medical Conditions and Women in Labor and Supporting Regulations Contained in 42 CFR 488.18, 489.20 and 489.24; *Document No.: HCFA–-R–142 (OMB*# 0938–0667); *Use:* The Information Collection Requirements contained in BPD–393, Examination and Treatment for Emergency Medical Conditions and Women in Labor contains requirements for hospitals to prevent them from inappropriately transferring individuals with emergency medical conditions, as mandated by Congress. HCFA will use this information to help assure compliance with this mandate and protect the public. This information is not contained elsewhere in regulations. *Frequency:* On occasion; *Affected Public:* Individuals or Households, Not-for-profit institutions, Federal