request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ann Borlo at (301) 986–4870 no later than November 1, 1997.

Dated: August 19, 1997.

Daniel C. Montoya,

Executive Director, Presidential Advisory Council on HIV and AIDS, Office of National AIDS Policy.

[FR Doc. 97–22533 Filed 8–22–97; 8:45 am]

BILLING CODE 3195–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

The Department of Health and Human Services has submitted the following (see below) emergency processing public information clearance request (ICR) to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (P.L. 104–13, 44 U.S.C. Chapter 35).

Title: State Annual Long-Term Care Ombudsman Report.

OMB Number: 0985–0005.

Instrument	Number of respondents	Number of responses per year	Average burden hours per respondent	Total burden hours
State Annual Long-Term Care Ombudsman Report.	52 State Agencies on Aging	Once per respondent per year	173	9,000

Description: To revise an existing information collection for States to use in reporting on activities of their Long-Term Care Ombudsman Programs as required under Section 712(b) and (h) of the Older Americans Act, as amended; the revisions:

(1) Modify the wording of some of the complaint categories to assist respondents in categorizing some complaints which were being placed under ''other;'' and

(2) Stipulate that several narrative responses which have not changed since the previous report do not need to be repeated.

The reporting system is for fiscal year 1997–99.

Additional Information: The AoA is requesting that OMB grant a 180-day approval for this information collection under procedures for emergency processing by August 29, 1997. A copy of this individual ICR, with applicable supporting documentation, may be obtained by calling the Administration on Aging, Reports Clearance Officer, Sharon Matthews at (202) 205–2814.

Comments and questions about the ICR should be directed to the Office of Information and Regulatory Affairs, Attn: Allison Herron Eydt, OMB Desk Officer, Office of Management and Budget, Room 10325, Washington, DC 20503.

Dated: August 14, 1997.

Alicia Valadez Ors,

Director, Office of Governmental Affairs and Elder Rights, Administration on Aging.

[FR Doc. 97–22417 Filed 8–22–97; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91F–0032]

Th. Goldschmidt A.G.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 1B4244) proposing that the food additive regulations be amended to provide for the safe use of silicone acrylate resins in coatings for metal substrates, polyolefin films, and paper and paperboard intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 4, 1991 (56 FR 9012), FDA announced that a food additive petition (FAP 1B4244) had been filed by Th. Goldschmidt A.G. (currently c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). The petition proposed to amend the food additive regulations to provide for the safe use of silicone acrylate resins for use in coatings for metal substrates, polyolefin films, and paper and paperboard intended for use in contact with food. Th. Goldschmidt A.G. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: August 7, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–22554 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–0331]

Guidance for Industry on Dissolution Testing of Immediate Release Solid Oral Dosage Forms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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 general recommendations for dissolution testing, approaches for setting dissolution specifications related to biopharmaceutic characteristics of the drug substance, statistical methods for comparing dissolution profiles, and a process to help determine when dissolution testing is sufficient to grant a waiver for an in vivo bioequivalence study. This guidance document also provides recommendations for dissolution tests to help ensure continuous drug product quality and performance after certain postapproval manufacturing changes.

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