advances will continue in the area of allergenic extracts and that this document may become outdated as those advances occur. This draft guidance document represents the agency's current thinking on testing limits in stability protocols for standardized grass pollen extracts.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Interested persons may submit written comments on the draft guidance document to the Dockets Management Branch (address above).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 The draft guidance document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday. Comments received will be considered in determining whether further revision of the draft guidance document is warranted.

Persons with access to the INTERNET may obtain the draft guidance document by using the World Wide Web (WWW).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

Government, and State, Local or Tribal Government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 1.

It should be noted for the HCFA–R–142, OMB 0938–0667, that based on industry input and HCFA analysis, the applicability and burden associated with the information collection requirements (ICR) captured in this submission have been adjusted to properly reflect the degree of burden associated with this collection. In particular, the ICRs captured in this submission have been determined to be either exempt or the burden has been deemed usual and customary in accordance with the 1995 PRA. In order to comply and properly reflect the Act, HCFA assigned a token one-hour of burden for this submission.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 18, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97–22451 Filed 8–22–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—Extension and Revision—Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), Limitation on Prices of Drugs Purchased by Covered Entities. Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Drug Pricing Program has developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

Audit guidelines: A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B. If the problem cannot be resolved, the manufacturer must then submit an audit work plan describing the audit to the HRSA Office of Drug Pricing Program for review. The manufacturer will submit copies of the audit report to the HRSA Office of Drug Pricing Program for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General. As a result of public comment on the draft audit guidelines, one of the requirements has changed. The manufacturer is no longer required to submit a request for an audit of a covered entity to the HRSA Office of Drug Pricing Program. Instead, the manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B.

Dispute resolution guidelines: Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Drug Pricing Program has developed a dispute resolution process which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a dispute with the HRSA Office of Drug Pricing Program, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA Office of Drug Pricing Program. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

To date, there have been no requests for audits, and no disputes have reached the level where a committee review was needed. As a result, the estimates of annualized hour burden for audits and disputes have been reduced to the level shown in the table below.

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/response	Total burden hours
Audits:					
Audit Notification of Entity [1]	2	1.0	2	4.0	8
Audit Workplan [1]	1	1.0	1	8.0	8
Audit Report [1]	1	1.0	1	1.0	1
Entity Response	0	0.0	0	16.0	0