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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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 The draft guidance document, when finalized, would provide information to FDA reviewers regarding broader relative potency limits for CBER evaluation of standardized dust mite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This draft guidance document represents the agency's current thinking with regard to the potency limits for standardized dust mite and grass allergen vaccines.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This draft document is being distributed for comment purposes only and is not intended for implementation at this time.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 May 15, 2000, 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: February 8, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–3407 Filed 2–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Grants for Hospital Construction and Modernization—Federal Right of Recovery and Waiver of Recovery (42 CFR, Subpart H) (OMB No. 0915–0099)—Extension

The regulation known as ''Federal Right of Recovery and Waiver of Recovery,'' provides a means for the Federal Government to recover grant funds and a method of calculating interest when a grant-assisted facility under Title VI and XVI is sold or leased, or there is a change in use of the facility. It also allows for a waiver of the right of recovery under certain circumstances. Facilities are required to provide written notice to the Federal Government when such a change occurs; and to provide copies of sales contracts, lease agreements, estimates of current assets and liabilities, value of equipment, expected value of land on the new owner's books and remaining depreciation for all fixed assets involved in the transactions, and other information and documents pertinent to the change of status.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Regulation	Number of respondents	Responses per respondent	Hours per response	Total burden hours
124.704(b) and 707	20	1	3	60

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: February 7, 2000.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–3409 Filed 2–14–00; 8:45 am]

BILLING CODE 4160–15–U

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: Maternal and Child Health Services Block Grant Annual Report, Needs Assessment and Application Guidance (OMB No. 0915–0172)—Revision

The Health Resources and Services Administration (HRSA) proposes to revise the Guidance and Forms for the Application and Annual Report for the Maternal and Child Health Services Title V Block Grant Program. The guidance is used annually by the 50 States and nine jurisdictions in making application for Block Grants under Title V of the Social Security Act, and in preparing the required annual report. The proposed revisions follow and build on extensive modifications made to the guidance and forms in 1997. The proposed revisions are of two types: (1) Editorial and technical revisions based on the experiences of the States and jurisdictions in using the guidance and forms in 1998 and 1999; and, (2) The addition of a standard set of measures to be used in conducting the formal needs assessment required by Title V every five years. This needs assessment will be required of each State and jurisdiction in fiscal year 2000.

The addition of the core set of measures for use in conducting the formal needs assessment follows discussions with State Maternal and Child Health Directors over the last two years. The changes incorporated in the 1997 revisions have been reflected in major changes in the Title V program, with much more emphasis on accountability and performance measurement as part of the performance partnership concept on which those changes were built. The inclusion now of standard measures for all States and jurisdictions to use in conducting the five-year needs assessment is a natural progression in the development of the Federal-State partnership process.

Following approval of the 1997 revisions, HRSA developed and instituted an automated electronic data collection and reporting system, the Title V Electronic Reporting Package (Title V ERP). The ERP has greatly reduced the burden on the States and jurisdictions, because it provides for automatic calculations of ratios, rates, and percentages, carries data over from year to year, and assures that data used in multiple tables are entered only once. The ERP also provides for text entry, and facilitates the orderly printing of tables, text, and required appendices.

The estimated response burden is as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Annual Report and Application with Needs Assessment (FY 2000):				
States	50	1	500	25,000
Jurisdictions	9	1	270	2,430
Annual Report and Application without Needs Assessment (FY 2001 and FY 2002)				
States	50	1	335	16,750
Jurisdictions	9	1	135	1,215
Total Average Annual Reporting Burden				21,122

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 7, 2000.

Jane Harrison

Director, Division of Policy Review and Coordination.

[FR Doc. 00–3408 Filed 2–14–00; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4420–D–07]

Redelegation of Authority for Review and Approval or Disapproval of PHA Plans

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Redelegation of Authority.

SUMMARY: In this notice, the Assistant Secretary for Public and Indian Housing redelegates the authority for review and approval or disapproval of the 5-year Plans and Annual Plans of a public housing agencies (PHAs) under 24 CFR part 903, and conducting all activities related to such review, approval or disapproval, to the Offices of Public Housing Hub Directors, Program Center Coordinators and to the Directors of Troubled Agency Recovery Centers, with exceptions.

EFFECTIVE DATE: January 28, 2000.

FOR FURTHER INFORMATION CONTACT: Rod Solomon, Office of Policy, Program and Legislative Initiatives, Office of Public and Indian Housing, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW, Room 4116, Washington, DC 20410. Telephone number: (202) 708–0713. This is not a toll-free number. This number may be