40099). The draft guidance discusses how the general provisions of the Quality System Regulation apply to software and the agency's current approach to evaluating a software validation system. The agency is taking this action in response to a request for an extension to allow additional time for comment on this draft guidance document.

DATES: Written comments by December 30, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: E. Stewart Crumpler, Center for Devices and Radiological Health (HFZ–343), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 25, 1997 (62 FR 40099), FDA announced the availability of a draft guidance entitled ''General Principles of Software Validation.'' The draft guidance discusses how the general provisions of the Quality System Regulation apply to software and the agency 's current approach to evaluating a software validation system. Interested persons were given until October 1, 1997, to submit written comments on the notice. FDA received a request from the Health Industry Manufacturers Association to extend the comment period for 90 days. This would give them sufficient time to review the document and ensure quality comments on the document.

FDA is extending the comment period for 90 days to assure adequate time for preparation of comments. Accordingly, FDA finds under section 520(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360j(d)) that there is good cause for such an extension.

Interested persons may, on or before December 30, 1997, submit to the Docket Management Branch (address above) written comments regarding the notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 28, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–25669 Filed 9–26–97; 8:45 am]

BILLING CODE 4160–01–F

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: Application and Annual Report, Maternal and Child Health Block Grant Program (OMB No. 0915–0172)—Extension and Revision

The Health Resources and Services Administration (HRSA) has revised and reformatted the Maternal and Child Health Block Grant Guidance. This guidance is used annually by the 50 States and 9 jurisdictions in making application for Block Grants under Title V of the Social Security Act, and in preparing the required annual report. The revisions are designed to simplify and clarify the guidance and required forms and to reduce duplication, while still allowing for clear, concise, useful, and accurate communication about the States' programs. More specifically, the revisions are designed to: (1) Make the program descriptions more readable; (2) alleviate the disconnect between the application for the next fiscal year and the annual report for the previous fiscal year that makes programmatic and data reviews difficult; (3) clarify budget and expense tables, through better design of forms and by carrying totals from form to form; (4) report objectives in a standard format, including the relationship to Healthy People 2000 goals, to facilitate year-to-year comparisons and multi-State tabulations; and, (5) incorporate uniform performance measures across all States and jurisdictions as well as State/jurisdiction-specific performance measures.

The HRSA revision also combines the current three guidance documents into one document by eliminating the separate annual application and annual report in favor of a combined document, and every fifth year explicitly including the results of the needs assessment, which would be incorporated only by reference in the intervening years. The HRSA revision efforts are intended not only to simplify and expedite the rational submission of necessary data and reports, but also to reduce the burden on States and jurisdictions by eliminating duplicative requirements and streamlining the presentation of information. Estimates of burden to complete the application and annual report are as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Application and Annual Report, 1998–99 (without needs assessment):*				
States	50	1	500	25,000
Jurisdictions	9	1	200	1,800
Five-Year Application and Annual Report, 2000 (with needs assessment): *				
States	50	1	750	37,500
Jurisdictions	9	1	400	3,600
Weighted Annual Average (over next three years):				
States	50	1	555	29,167
Jurisdictions	9	1	267	2,400

*The Annual Application and Annual Report, without needs assessment, will be submitted in FY 1998 and FY 1999. The five-year Annual Application and Annual Report will be submitted in FY 2000. The average annual response burden for the next three years is 31,567 hours.

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

Dated: September 22, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97–25727 Filed 9–26–97; 8:45 am]

BILLING CODE 4160–15–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: Ryan White Comprehensive AIDS Resources and Emergency (CARE) Act Women's Initiatives (WIN)—New

The Health Resources and Services Administration's HIV-AIDS Bureau proposes to collect information about HIV-related services provided to women of child-bearing age and their children. Information will be collected annually from eight grantees funded under Sections 2671 and 2691 of the Public Health Service Act and 320 of the individual and institutional providers who provide services to HIV-infected pregnant women in the grantee service areas. The eight funded sites will collect the information in person or by telephone from the providers in their service areas, and forward the data collection forms to a HRSA contractor. There are no plans to collect or transmit the data electronically.

The purpose is to document current care system characteristics and facilitate planning for services to women with HIV and their children. The information will be used within and outside HRSA to inform the administration and Congress about HIV counseling and testing services for pregnant women, services and referral resources for pregnant women with HIV, antiretroviral therapies, and outreach related to perinatal HIV transmission reduction. Annual burden estimates are as follows:

Type of respondent	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Providers	320	1	.75	240
Funded Sites	8	40	1	320
Total	328			560

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

Dated: September 22, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97–25729 Filed 9–26–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings:

Name of SEP: Magnesium in Coronaries (MAGIC).

Date: October 15–16, 1997.

Time: 7:00 p.m.

Place: Holiday Inn Gaithersburg, 2 Montgomery Village Avenue, Gaithersburg, Maryland 20814.

Contact Person: Anthony M. Coelho, Ph.D., Two Rockledge Center, Room 7182, 6701 Rockledge Drive, Bethesda, MD 20892–7956, (301) 435–0288.

Purpose/Agenda: To review and evaluate contract proposals.

Name of SEP: Demonstration and Education Research Applications (R18).

Date: October 28, 1997.

Time: 8:30 a.m.

Place: Washington National Airport Hilton, 2399 Jefferson Davis Highway, Arlington, Virginia 22202.

Contact Person: Louise Corman, Ph.D., Two Rockledge Center, Room 7180, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0270.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: September 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–25704 Filed 9–26–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice