information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Doria DuBois, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION:

I. Background

On February 12, 1998, FDA called a meeting of the Microbiology Devices Advisory Panel to obtain recommendations from the panel regarding scientific information necessary for premarket approval of tests for hepatitis viruses. Following the panel meeting and subsequent discussions between FDA and industry, FDA developed and published a draft guidance (See 64 FR 54902, October 8, 1999). FDA accepted public comments regarding the draft guidance until January 6, 2000. This second draft guidance incorporates those comments and replaces the October 8, 1999, draft guidance document.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on assays for detecting evidence of infection with HCV. 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 applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs) and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1353) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection or HCV-Associated Disease; Draft Guidance for Industry and FDA,'' will be available at http://www.fda.gov/cdrh/ode/guidance/1353.pdf. Updated on a regular basis, the CDRH home page also includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by July 26, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 18, 2001.

Linda S. Kahan,

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

[FR Doc. 01–10528 Filed 4–26–01; 8:45 am]

BILLING CODE 4160–01–S

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, Pub. L. 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) 443–1891.

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: Evaluation of the Health Care for the Homeless Respite Pilot Initiative—New

The Bureau of Primary Health Care (BPHC), Health Resources Services Administration (HRSA), proposes to conduct an evaluation of the Health Care for the Homeless (HCH) Respite Pilot Initiative. Data will be collected from the ten HCH grantees participating in the Pilot Initiative. The evaluation will be developed and conducted by the National Health Care for the Homeless Council through a cooperative agreement with the BPHC. The focus of the evaluation will be on assessing the effect of respite services on the health of homeless people as well as looking at any differences in outcomes based on client or program characteristics. The evaluation will be conducted throughout the three-year period of the Pilot Initiative.

The estimated response burden is as follows:

Type of respondent	Number of respondents	Response per respondents	Hours per response	Total hour burden
HCH Grantees	10	600	0.25	1500

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received on or before June 26, 2001.

Dated: April 23, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–10529 Filed 4–26–01; 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: Uniform Data System (OMB No. 0915–0193)—Revision—This is a request for revision of approval of the Uniform Data System (UDS), which contains the annual reporting requirements for the cluster of primary care grantees funded by the Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Outreach and Primary Health Services for Homeless Children and Public Housing Primary Care. Authorizing Legislation is found in Public Law 104–299, Health Center Consolidation Act of 1996, enacting Section 330 of the Public Health Service Act.

The Bureau of Primary Health Care collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The UDS includes two components: the Universal Report, completed by all grantees, provides data on services, staffing, and financing; and the Grant Report, completed by grantees funded under the Homeless or Public Housing Program as well as one of the other programs, provides data on characteristics of users whose services fall within the scope of the Homeless or Public Housing Program grant. Grantees are also asked to provide information on the charges, collections, bad debt write off and contractual disallowances by payor sources (Medicaid, Medicare, self pay and private insurance). In addition, grantees need to include categories to some of the lists (*e.g.,* services, ICD codes, CPT codes) and annotating the forms to indicate which lines are subtotals and the lines to which they sum.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Hours per response	Total burden hours
Universal	712	24	17,088
Grant	96	16	1,536
Total	712		18,624

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

Dated: April 23, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–10531 Filed 4–26–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Federal Assistance to the Columbia Hospital for Women Medical Center Community Outreach Programs

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of grant award.

SUMMARY: The Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA), awarded a grant for $5 million in fiscal year (FY) 2001 to Columbia Hospital for Women Medical Center, in Washington, DC. The grant supports community outreach programs for women. The award was made from funds appropriated under Public Law 106–554 (HHS Appropriation Act for FY 2001). As part of MCHB's overall appropriation, monies were specifically designated to support the Columbia Hospital for Women Medical Center project. The grant for the project is a Special Project of Regional and National Significance authorized by section 501(a)(2) of the Social Security Act, the Maternal and Child Health Federal Set-Aside Program.

SINGLE SOURCE JUSTIFICATION: The HRSA is providing Federal financial assistance to the Columbia Hospital for Women Medical Center to support infrastructure development of community outreach programs for women (and their high risk infants), to: (1) Maintain capacity and increase coordination of primary care and preventive services for women and high risk infants who have limited