administered drug products in INDs, NDAs, ANDAs, and supplemental applications. This guidance provides recommendations for when studies are appropriate, as well as recommendations on study design, data analysis, and product labeling.

In the **Federal Register** of November 28, 2001 (66 FR 59433), FDA published a draft guidance entitled ''Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling.'' Based on comments received on the draft guidance and the refinement of agency thinking on the conduct of such studies, FDA has revised the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on submitting food-effect BA and fed BE information as part of INDs, NDAs, and ANDAs. 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 and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed 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. The guidance 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 either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: January 21, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2214 Filed 1–30–03; 8:45 am]

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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 the 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 Office of Management and Budget (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 at (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: Ryan White CARE Act: Title III Client-level Demonstration Project (CDP)—New

The CDP was originally established in 1994 to collect information from grantees and their subcontracted service providers funded under Titles I and II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, as amended by the Ryan White CARE Act Amendments of 1996 (codified under Title XXVI of the Public Health Service (PHS) Act). This new effort will collect client level data from a sample of Ryan White CARE Act Title III Grantees. The HRSA's HIV/AIDS Bureau administers funds for all titles of the CARE Act. The Title III program is authorized by Section 2651 of the PHS Act.

The PHS Act specifies that HRSA is responsible for the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quantity and quality of care. Accurate records on the grantees receiving CARE Act funding, the services provided, and the clients served are critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities.

Client level information will be collected from a sample of Title III CARE Act funded grantees regarding the number of clients served, services provided, demographic information about clients served, and health status of clients served. In addition, client level information will be collected that measures mortality status and additional indicators of health status and whether standards of care are being followed by providers.

The primary purposes of the CDP are to examine client level demographic and service data on HIV/AIDS infected/affected clients being served by the Ryan White CARE Act and demonstrate the usefulness of these data for planning and evaluation purposes at both the local and national levels. Through this system, HRSA seeks to supplement the information collected in the CARE Act Data Report (CADR). Because there is no nationwide acceptance of client level reporting for HIV/AIDS services, the CADR collects data aggregated at the grantee level and contains duplicated counts of clients who have received services from more than one provider during a given reporting period.

Based on data from eligible grantees, the number of clients that a grantee serves ranges from 125 to 2748, with 422 being the median number of clients. About 30 minutes is required to respond to these questions and the data are collected 4 times a year.

The burden estimate for this project is as follows:

Grantee	Number of respondents	Responses per respondent	Total responses	Burden hour per respondent	Total burden hours
<500 Clients	15	250	3,750	2	7,500
500+ Clients	10	1,232	12,320	2	24,640
Total	25	.....	16,070	.....	32,140

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–45, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: January 23, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–2215 Filed 1–30–03; 8:45 am]

BILLING CODE 4165–15–P

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: Uniform Data System (OMB No. 0915–0193)—Revision

This is a request for a 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). Authorizing Legislation is Section 330 of the Public Health Service Act. 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, and Healthy Schools Healthy Communities. BPHC collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policy makers 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, Public Housing Program or Healthy Schools Healthy Communities as well as one of the other programs, provides data on characteristics of users whose services fall within the scope of the Homeless, Public Housing Program, Healthy Schools Healthy Communities 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).

Estimated annualized reporting burden are as follows:

Type of report	Number of respondents	Hours per response	Total burden hours
Universal Report	982	27	26,514
Grant Report	184	18	3,312
Total	982	.....	29,826

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 27, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–2349 Filed 1–30–03; 8:45 am]

BILLING CODE 4165–15–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 (OMB), 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: Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration—(OMB 0915–0212)—Extension

In response to Executive Order 12862, the Health Resources and Services Administration (HRSA) is proposing to conduct voluntary customer surveys of its ''partners'' to assess strengths and weaknesses in program services. A generic approval is being requested from OMB to conduct the partner surveys. HRSA partners are typically State or local governments, health care facilities, health care consortia, health care providers, and researchers.

Partner surveys to be conducted by HRSA might include, for example, mail or telephone surveys of grantees to