all amendments and supplements thereto on the ground that the applicants have failed to submit the reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed above should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) On or before April 11, 1996, a written notice of participation and request for a hearing, and (2) on or before May 13, 1996, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing, are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved mew drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m, Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: February 28, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–5748 Filed 3–11–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; 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 summary of proposed collection for public comment. Interested persons are invited to send comments regarding the 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Payment Adjustment for Sole Community Hospitals; *Form No.:* HCFA–R–79; *Use:* Hospitals designated as ''Sole Community Hospitals'' that experience a five percent decrease in discharges in one cost reporting period, as compared to the previous period, due to unusual circumstances, beyond its control, may request an adjustment to its Medicare payment amount. *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 40; *Total Annual Responses:* 40; *Total Annual Hours Requested:* 160.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 4, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.

[FR Doc. 96–5772 Filed 3–11–96; 8:45 am]

BILLING CODE 4120–03–P

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:

Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Title IV—The Maternal and Child Health Bureau (MCHB) proposes to collect aggregated data from 38 grantees and their 72 local service providers that are funded under Section 2671 of the Public Health Service Act (42 U.S.C. 300ff–71). Data will be collected from grantees and providers on the organizational structures, service delivery approaches, numbers and demographic characteristics of clients served, service utilization, and activities related to outreach, prevention, and education. The data collection strategy includes six tables that the grantees and their local

service providers will use to submit information annually about program and client characteristics. The data collected will be used within and outside MCHB and HRSA to inform the administration and Congress about the Title IV program and will be used by grantees and MCHB for other planning and policy efforts. Burden estimates are as follows:

Type of form	Number of respondents	Responses per respondent	Average hours per response	Total burden hours
Designation of Local Reporting Entities	38	1	0.5	19
Local Network Profile	110	1	.5	55
Service Mix Profile	110	1	2.8	308
Demographic and Clinical Status	110	1	33.0	3,630
Service Utilization Summary	110	1	20.0	2,200
Prevention and Education Activities	110	1	4.0	440

Estimated Total Annual Burden: 6652 hours.

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

Dated: March 6, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–5811 Filed 3–11–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

Proposed Data Collection; Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects. To request more information on the proposed project, call Amy F. Subar, Ph.D., Nutritionist, or Susan M. Krebs-Smith, Ph.D., Nutritionist, at (301) 496–8500.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proposed 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. Send comments to Amy F. Subar, Ph.D., Susan M. Krebs-Smith, Ph.D., National Cancer Institute, EPN 313, 6130 Executive Blvd., MSC 7344, Bethesda, MD 20892–7344. Written comments should be received by (Federal Register insert the data 60 days following the date of publication).

Proposed Project: Followup Survey of the National 5 A Day for Better Health Program—New—This study will measure five year trends in fruit and vegetable intakes and in knowledge, attitudes, and benefits about diet and nutrition specific to fruit and vegetable intake. The purpose of this study is to evaluate the effectiveness of the National 5 A Day for Better Health Program in the first five years of its existence. Two questionnaires will be administered concurrently via telephone to separate national samples of households, with an oversampling of African Americans and Hispanics. Methods, sampling, and techniques will be as similar as possible to that conducted in the original Baseline Survey. The difference between the samples will be in the survey instruments administered. The first, long questionnaire is the instrument used in the original 5 A Day Baseline Survey. The second, short questionnaire will obtain similar information to that collected using the long questionnaire. Because of concern for response rates and possible biases associated with low response rates, a survey of non-respondents from the long survey will also be conducted. This survey will use methods as similar as possible to those employed in the non-respondent survey to the 1991 Baseline Survey. Study participants will be U.S. adults 18 years and old residing in these coterminous states. Burden estimates are as follows:

	No. of respondents	Instrument type	No. of responses per respondent	Avg burden/response
Group 1	2,000	Long	1	.501 hrs.
Group 2	2,050	Short	1	.251 hrs.
Non-Response	150	Response	1	.167 hrs.

Dated: March 1, 1996

Philip D. Amoruso,

NCI Executive Officer.

[FR Doc. 96–5760 Filed 3–11–96; 8:45 am]

BILLING CODE 4140–01–M

Submission for OMB Review; Preventing Problem Behavior Among Middle School Students; Comment Request

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection