and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–3937, or
Robert A. Yetter, CBER (HFM–25), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a guidance for industry entitled ''Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under PDUFA.'' In conjunction with the June 2002 reauthorization of PDUFA, FDA agreed to meet specific performance goals (PDUFA Goals). The PDUFA Goals include two pilot programs to explore the continuous marketing application (CMA) concept. The CMA concept builds on the current practice of interaction between FDA and applicants during drug development and application review and proposes opportunities for improvement.

In the **Federal Register** of June 17, 2003 (68 FR 35903), FDA announced the availability of a draft version of this guidance. FDA received a number of comments on the draft guidance. We have considered the comments carefully and have made some changes to address those comments. Among other things, we have revised the guidance to further describe the selection of marketing applications for inclusion in Pilot 1, clarify the content and submission process for reviewable units, and provide for public availability of additional information during the program.

Under the CMA pilot program, Pilot 1, applicants submitting new drug applications or biological licensing applications for products that have been designated as Fast Track drug or biological products (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) may be eligible to submit portions of their marketing applications (reviewable units) in advance of the complete marketing application. FDA has agreed to complete reviews of reviewable units within a specified time and to provide early feedback for those presubmissions in the form of discipline review letters.

This guidance provides information on how the agency will implement Pilot 1. As described in the guidance, Pilot 1 is an exploratory program that will allow FDA to evaluate the added value, costs, and impact of early review and feedback on parts of applications (reviewable units) in advance of submission of the complete application.

This level 1 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 the implementation of the Pilot 1 program for reviewable units of certain Fast Track drug and biological products. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet can obtain the guidance at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/cber/guidelines.htm*.

Dated: September 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25306 Filed 10–1–03; 4:09 pm]

BILLING CODE 4160–01–S

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.

Proposed Project: HRSA AIDS Education and Training Centers Evaluation Activities—NEW

The AIDS Education and Training Centers (AETC) Program, under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, supports a network of regional and cross-cutting national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV/AIDS. The AETCs' purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

As part of a national evaluation effort of AETC activities, one questionnaire and several record-keeping forms have been developed to capture information on AETC activities. The first form is the Participant Information Form and asks trainees for information on the individual's profession, type of clinical practice, and patient population. Recordkeeping forms include (1) the Program Record which records information such as topic, training time, number of people reached, and format per training activity, (2) the Clinical Consultation Form which collects information on consults with a provider regarding a specific patient, (3) the Group Clinical Consultation Form which records information on the nature of the cases discussed and the session format during a site visit, and (4) the Agency Technical Assistance Form which collects information on activities to improve non-clinical aspects of care (*e.g.*, medical records, resource allocation). The information on the recordkeeping forms comprises a core data set that will be submitted to the HIV/AIDS Bureau (HAB) data contractor three times per year.

Each center will be required to report aggregate data from these forms on their activities to HRSA/HAB. This data collection will provide information on the number of training, consultation, and technical assistance activities by center, the number of health care providers receiving professional training or consultation, the time and effort expended on different types of training and consultation activities, the populations served by the AETC trainees, and the increase in capacity achieved through training and technical assistance activities. Collection of this information will allow HRSA/HAB to provide information on training activities, types of education and

training provided to Ryan White CARE Act grantees, resource allocation, and capacity expansion.

Trainees will be asked to complete the Participant Information Form for each activity they complete. The estimated annual response burden to attendees of training programs is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Participant Information	75,000	2	150,000	0.2	30,000

The estimated annual burden to AETCs is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Program Record	12	500	6,000	0.1	600
Clinical Consultation	12	300	3,600	0.1	360
Group Clinical Consultation	12	75	900	0.1	90
Technical Assistance	12	250	3,000	0.1	300
Aggregate Data Set	12	3	36	32	1,152
Total	12		13,536		2,502

The total burden hours being requested are 32,502.

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: September 30, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–25250 Filed 10–3–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Cancer Institute Science Enrichment Program Surveys

Summary: 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 Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NCI Science Enrichment Program (SEP) Surveys.

Type of Information Collection Request: New.

Need and Use of Information Collection: NCI SEP is a 5-week summer residential program on university campuses that serves under-represented minority and under-served students who have just completed ninth grade.

The program goals are to: (1) Encourage student participants to select careers in science, mathematics, and/or research, and (2) broaden and enrich students' science, research, and sociocultural backgrounds. The proposed data collection encompasses three surveys: (1) A follow-up survey of SEP and control group students who participated in a five-year longitudinal evaluation of the program conducted between 1998 and 2003; (2) a post-program survey of parents of SEP 2004 participants; and (3) a follow-up survey of SEP 1990–1997 alumni. The information from the proposed data collection will supplement previous evaluation results, which have been and will continue to be used to judge program process and outcomes.

Frequency of Response: One time.

Affected Public: Individuals or households.

Type of Respondents: High school and college students, young adults, and parents of high school students participating in the program.

Cost to Respondents: $4,070.

The annual reporting burden is as follows:

ESTIMATES OF HOUR BURDEN: BURDEN REQUESTED

Type of respondents	Average number of respondents/Yr.	Frequency of response	Average time per response	Average annual hour burden
SEP Participants	600	1	0.25	150
Control Group Students	300	1	0.25	75
Parents of SEP Participants	100	1	0.25	25
SEP 1990–1997 Alumni	627	1	0.25	157
Total	1,627			407