populations of HIV positive individuals or persons infected with other serious diseases, far outweigh any risk to the individual's health posed by the test kit protocol or to the public's health by home testing. BPAC recommended that pilot studies be conducted to assess demographically, qualitatively, and quantitatively the effectiveness of test kits in targeted populations. BPAC also recommended that pilot studies be performed to determine the effectiveness of such services in ensuring client anonymity and providing adequate counseling. CBER considered the BPAC recommendations during its review of the premarket approval application for the Home Access® HIV–1 Test System. On July 22, 1996, CBER approved the application by a letter to the applicant from the Director, Office of Blood Research and Review, CBER.

The July 22, 1996, application approval letter restated postapproval conditions agreed to by HAHC in three letters to FDA dated June 19, 1996, and July 12 and 22, 1996. These conditions incorporate the June 22, 1994, BPAC recommendations. The postapproval conditions include the following: (1) HAHC will perform postmarketing monitoring studies and, after consultation with CBER, submit a detailed study protocol within 30 days of the product's entry into interstate commerce; (2) HAHC will qualify all test kits and perform acceptance testing on all lots to be used with the Home Access® HIV–1 Test System, including the Vironostika HIV–1 Microelisa System® manufactured by Organon Teknika Corp. and Fluorognost HIV–1 IFA® manufactured by Waldheim Pharmazuetika; (3) HAHC will not use Genetic Systems Corp. LAV EIA until the reagents for that assay have passed lot acceptance protocols; (4) HAHC will not commercialize the ''Standard Kit'' until transport claims for the U.S. Mail have been verified to have an acceptable rate of loss; (5) HAHC will change the accuracy claim of the Home Access® HIV–1 Test System from ''greater than 99.99% accurate'' to ''greater than 99.9% accurate;'' and (6) the package insert will be revised as described in a July 12, 1996, letter.

A summary of the safety and effectiveness data on which CBER based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CBER's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before February 26, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 7, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–1852 Filed 1–24–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Document Identifier: HCFA–643]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 collections 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.

1. HCFA–643 *Type of Information Collection Request:* Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations 42 CFR Sections 488,488.26(c), 442.30(a)(4), 442, Subpart B,C,D,E and F; *Form No.:* HCFA 643; *Use:*. The survey report form and supporting regulations are needed to ensure provider compliance. In order to participate in the Medicare program, a hospice must meet certain Federal health and safety conditions of participation. The survey report form will be used by State surveyors to record data about a hospice's compliance with these conditions of participation in order to initiate the certification or recertification process. *Frequency:* Annually; *Affected Public:* State, Local or Tribal Govt, Federal Govt; *Number of Respondents:* 2,150; *Total Annual Responses:* 2,150; *Total Annual Hours:* 5,375.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed 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 Analysis and Planning Staff, Attention: John Rudolph, Room C2–25–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 15, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97–1917 Filed 1–24–97; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Healthy Start Cooperative Agreements

AGENCY: Health Resources and Services Administration (HRSA).

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that approximately $54 million dollars in fiscal year (FY) 1997 funds will be available for cooperative agreements to communities for the replication phase of the Healthy Start Initiative, hereafter called Healthy Start-Phase II. The Healthy Start Initiative is a program of projects which, since FY 1991, has developed and implemented community-based strategies to reduce infant mortality in areas with a high incidence of infant mortality. The purpose of Healthy Start-Phase II is to operationalize successful infant mortality reduction strategies developed during the demonstration phase and to launch Healthy Start projects in new rural and urban communities (i.e., communities currently without a Healthy Start-funded project). Competition is open to community-based entities interested in replicating or adapting existing Healthy Start models with assistance from selected Healthy Start projects already in operation. The project period is four years, subject to continuing availability of funds.

Within the HRSA, the Healthy Start Initiative is administered by the Maternal and Child Health Bureau (MCHB). Cooperative agreements for Healthy Start-Phase II will be made under the program authority of Section 301 of the Public Health Service Act. Funds for these awards were appropriated under Public Law 104–208.

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS led national activity for setting priority areas. The Healthy Start-Phase II program will directly address the Healthy People 2000 objectives related to maternal and infant health, and especially health status objective 14.1, to reduce the infant mortality rate to no more than 7 per 1000 live births. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402–9325 (telephone 202 783–3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products.

In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

ADDRESSES: The Federal Register notices and application guidance for the Healthy Start program are available on the World Wide Web via the Internet at address: http://www.os.dhhs.gov/hrsa/mchb. Click on the file name you want to download to your computer. It will be saved as a self-extracting Macintosh or WordPerfect 5.1 file. To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a WordPerfect 5.1 file.

For applicants for Healthy Start cooperative agreements who are unable to access application materials electronically, a hard copy (Revised PHS form 5161–1, approved under OMB clearance number 0937–0189) must be obtained from the HRSA Grants Application Center. Requests should specify the category or categories of activities for which an application is requested so that the appropriate forms, information and materials may be provided. The Center may be contacted by: Telephone Number: 1–888–300–HRSA, FAX Number: 301–309–0579, E-mail Address: HRSA.GAC@x.netcom.com. Completed applications should be returned to: Grants Management Officer (CFDA #93.926), HRSA Grants Application Center, 40 West Gude Drive, Suite 100, Rockville, Maryland 20850.

DATES: The application deadline date is April 15, 1997. Applications will be considered to be on time if they are either: (1) Received on or before the deadline date, or (2) postmarked on or before the deadline date and received in time for orderly processing. Applicants should request a legibly dated receipt from a commercial carrier or the U.S. Postal Service, or obtain a legibly dated U.S. Postal Service postmark. Private metered postmarks will not be accepted as proof of timely mailing. Late competing applications or those sent to an address other than that specified in the **ADDRESSES** section will be returned to the applicant.

FOR FURTHER INFORMATION: Requests for technical or programmatic information should be directed to Thurma McCann, M.D., M.P.H., Director, Division of Healthy Start, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 11–A–05, Rockville, Maryland 20857, telephone 301–443–0543. Requests for information concerning administration and business management issues should be directed to Sandy Perry, Chief, Grants Management Branch, Maternal and Child Health Bureau, 5600 Fishers Lane, Room 18–12, Rockville, Maryland, 20857, telephone 301–443–1440.

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

The Healthy Start Initiative was established as a demonstration program in 1991, based on the premise that new community-based strategies were needed to attack the causes of infant mortality and low birthweight especially among high risk populations.

Currently, there are 22 Healthy Start demonstration projects that have developed strategies to reduce infant mortality in their respective communities. Several of these strategies have been highly effective in achieving project objectives.

Approved applicants for this competition must agree to receive peer mentoring from existing Healthy Start grantees regarding the replication or adaptation of one or more of the strategies identified below. These strategies are categorized into nine intervention models (one organizational and eight service):

1. *Community-Based Consortium*—Establishment of a local community-based consortium/advisory board/coalition (consortium) of consumers (i.e., recipients of project services within the catchment area), providers, and others in an advisory capacity for program planning, operations, monitoring, and evaluation.

2. *Family Resource Center*—Provision of a community driven comprehensive array of client services at a single site at an accessible community location.