Dated: January 14, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–1849 Filed 1–24–97; 8:45 am]

BILLING CODE 4140–01–M

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care Biannual Aggregate Report.

OMB No.: New Collection.

Description: This legislatively mandated report collects program and participant's data on all children and families receiving direct CCDF services. Aggregate data will be collected and will be used to determine the scope, type, and methods of child care delivery, and to provide a report to Congress.

Respondents: State governments, Guam, Virgin Islands, Puerto Rico and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–800	54	2	40	4,320

Estimated Total Annual Burden Hours: 4,320

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: January 21, 1997.

Douglas J. Godesky,

Reports Clearance Officer.

[FR Doc. 97–1851 Filed 1–24–97; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96M–0456]

Home Access Health Corp.; Premarket Approval of the Home Access® HIV–1 Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Home Access Health Corp. (HAHC), Hoffman Estates, IL, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Home Access® HIV–1 Test System. After reviewing the recommendation of the Blood Products Advisory Committee (BPAC), FDA's Center for Biologics Evaluation and Research (CBER) notified the applicant, by letter of July 22, 1996, of the approval of the application.

DATES: Petitions for administrative review by February 26, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sukza Hwangbo, Center for Biologics Evaluation and Research (HFM–380), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3524.

SUPPLEMENTARY INFORMATION: On June 1, 1995, HAHC, Hoffman Estates, IL 60195–5200, submitted to CBER an application for premarket approval of the Home Access® HIV–1 Test System. This product is intended for self-use by individuals who wish to obtain anonymous human immunodeficiency virus Type 1 (HIV–1) testing and counseling. The HIV–1 assay kits approved for use in the Home Access® HIV–1 Test System are: (1) The Vironostika HIV–1 Microelisa System® manufactured by Organon Teknika Corp.; (2) the Genetic Systems LAV EIA HIV–1 enzyme immunoassay (EIA) manufactured by Genetic Systems; and (3) the Fluorognost® HIV–1 immunoflourescence assay (IFA) manufactured by Waldheim Pharmazuetika. The HAHC testing service consists of: (1) The Home Access® HIV–1 Home Collection Kit; (2) Client*trak*™ (Interactive Voice Response System, automated HIV/acquired immune deficiency syndrome (AIDS) educational announcement, and client database); (3) laboratory testing; and (4) counseling and referral services. Each collection kit contains: An instruction manual, an HIV/AIDS educational booklet in English and Spanish, a blood spot collection card precoded with a unique 11-digit Home Access® code number, two safety lancets, an alcohol wipe, a sterile gauze pad, a bandage, a foil return pouch containing a desiccant, a safety lancet disposal container, a shipping container, and a preaddressed and prepaid return envelope. The test procedure begins when the client activates a unique 11-digit code number by calling a toll-free telephone number. Clients use the kit to obtain samples of their own blood which is placed on the collection card that is precoded with the code number. The collection card is mailed to HAHC using the provided mailer. Upon receipt, the sample is analyzed using enzyme linked immunosorbent assays licensed for the detection of HIV–1 antibodies. Test results are available to the client from HAHC within 3 business days after shipment of the sample to the laboratory for the Express Kit and within 7 days for the Standard Kit. The service is recommended for use by individuals 18 years of age or older.

On June 22, 1994, CBER consulted BPAC, an FDA advisory committee, for their comments and recommendations regarding issues FDA should address when reviewing home collection testing kits for the detection of HIV and other serious or life-threatening medical conditions. BPAC commented that the benefits of an alternative means of accessing previously unreachable

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