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