DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

July 22, 1996

Michael Wandell, Pharm. D.
Home Access Health Corporation
2401 West Hassell Road, Suite 1510
Hoffman Estates, IL 60195-5200

Re: BP950002
Product: Home Access™ HIV-1 Test System
Filed: June 1, 1995
Amended: January 29, 1996; February 22, 1996; April 23, 1996; May 3, 1996; June 10, 1996; July 12, 1996, and July 22, 1996

Dear Dr. Wandell:

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for Home Access HIV-1 Test System using dried blood spots. This device is indicated for self-use by people who wish to obtain anonymous HIV testing. The service is recommended for use by people 18 years of age or older. The HIV-1 assay kits approved for use in the Home Access HIV-1 Test System are Vironostika HIV-1 Microelisa System manufactured by Organon Teknika Corporation, Genetic Systems LAV® EIA HIV-1 enzyme immunoassay(EIA) by Genetic Systems Corporation, and Fluorognost HIV-1 immunofluorescence assay (IFA) test by Waldheim Pharmazeutika. We are pleased to inform you that the PMA is approved subject to the specific conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The specific post-approval conditions to which you have agreed in your June 19, July 12, and July 22, 1996 letters include the following:

I. Post-marketing Surveillance Studies:

Home Access Health Corporation (HAHC) will perform post-marketing monitoring studies outlined in your June 19 letter. HAHC commits to cooperate with CBER to further refine the proposed study and submit a detailed study protocol within 30 days of entry of the product into interstate commerce.

The primary objectives of this study will be to (1) verify the safety and efficacy of the Home Access HIV-1 Test System under conditions of routine use so as to provide early warning, should unexpected incidence of adverse events occur, and (2) assess the public health impact of the product by comparing test result utilization and acceptance of health care referrals between public health clients and Home Access clients. These two questions will be studied for one year post-approval, subject to assessment at the end of the year by FDA/HAHC.

A minimum of four state or local public health agencies will participate in the study with about 25,000 clients over one year. Specific inclusion/exclusion criteria will be developed with a full knowledge of the participating study sites in order to provide the most statistically powerful comparison groups.

A secondary objective of the study is to augment public health surveillance efforts by tracking the number of HIV tests performed and their results, the demographic and risk profile of the users, the number of patients seeking initial evaluation for HIV infection and incidence of adverse consequences. Demographic and risk behavior data (both the state and national level) that will be solicited from all clients with positive or indeterminate results are as follows: gender, race/ethnicity, age, geographic location (zip code), and prior HIV-1 test results, receipt of blood or blood products, and injectable drug use. Similar information will be solicited, on a nationwide basis, from a random subset of clients who test negative.

The data analyses from the above studies will be submitted in the post-approval reports to the FDA and participating local public health agencies. The survey will be conducted during the three years post-approval, subject to an annual assessment of its value by FDA/HAHC.

II. Lot Acceptance & Proficiency Testing:

As an ongoing commitment, HAHC will take full responsibility for product qualification and acceptance testing for all test kit lots utilized with the Home Access HIV-1 Test System including Vironostika HIV-1 Microelisa System (Organon Teknika Corporation) and Fluorognost HIV-1 IFA (Waldheim Pharmazeutika).

Proficiency testing will be conducted as described in the protocols for the above two test kits. HAHC will not authorize its laboratory to use the Genetic Systems LAV EIA until such time that these lot acceptance procedures have been applied to those reagents.

III. "Standard Kit" Mail Study:

In response to an observation of an excessive rate of test specimen loss observed during a "U.S. Mail Time to Receipt Study," HAHC will commercialize only the "Express Kit" at the present time. The "Standard Kit" will not be distributed until such time that the U.S. Mail transport claims have been verified with an acceptable rate of loss.

IV. Accuracy Claim:

HAHC will change the accuracy claim of Home Access HIV-1 Test System from "greater than 99.99% accurate" to "greater than 99.9% accurate" as you committed to correct in the July 22 letter. Also, the package insert will be revised as described in your July 12 letter.

Expiration dating for this device has been granted for two years at room temperature. The final product real time stability study shall be conducted on three finished kit lots, and the data analyses will be submitted in the post-approval reports.

CBER will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the Act.)

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Act.

You are reminded that as soon as possible you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

Document Control Center (HFM-99)
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852

If you have any questions concerning this approval order, please contact Ms. Sukza Hwangbo, R.Ph., Biologics Devices Branch, Division of Blood Applications, Office of Blood Research and Review at 301-827-3524.

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research
and Review
Center for Biologics
Evaluation and Research

CONDITIONS OF APPROVAL(OTC)

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, Maryland 20852-1448

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual post-approval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POST-APPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of post-approval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Post-approval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, Maryland 20852-1448. The post-approval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Post-approval Reports" above unless specified otherwise in the conditions of approval to this PMA. This post-approval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857