DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 11, 2002

Ms. Marta Chase
Bayer Corporation
P.O. Box 2466
Berkeley, California 94702-0466

Re: BP000028/0
Product: The VERSANT [R] HIV-1 RNA 3.0 Assay (bDNA)
Device Code: MZF

Date Received: 09-MAY-00

Dear Ms. Chase:

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 the VERSANT [R] HIV-1 RNA 3.0 Assay (bDNA). This device is indicated for the direct quantitation of human immunodeficiency virus type 1 (HIV-1) RNA in plasma of HIV-1 infected individuals. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

Lot Acceptance Testing:

Bayer Corporation will provide lot release test results for the first three commercial lots of VERSANT [R] HIV-1 RNA 3.0 Assay (bDNA) Test. Thereafter, lot release data will be submitted to the Agency from every third lot of VERSANT [R] HIV-1 RNA 3.0 Assay (bDNA) Test kits for a period of 12 months under a surveillance program. The need for continued surveillance of this test kit beyond this period will be determined by the Agency.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order; and (2)

insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for this device has been established and approved at 12 months for storage of various components at 2-8°C, 2-30°C, or –60° to –80°C, as specified in the "Materials Provided" section of the package insert. You will be expected to monitor the stability of the device by means of a routine stability program consisting of evaluation of every fourth kit lot produced (not to exceed three kit lots tested per year).

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 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, and before commercial distribution of your device, 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, Maryland 20852-1448

If you have any questions concerning this approval order, please contact Dr. Sayah Nedjar at (301) 827-3524.

Sincerely,

Hiralal Nakhasi

Hira L. Nakhasi, Ph.D.
Director
Division of Emerging and Transfusion
Transmitted Diseases
Office of Blood Research and Review
Center for Biologics
Evaluation and Research