DEPARTMENT OF HEALTH & HUMAN SERVICES

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

AUG 0 5 2003

Our STN: BL *12503010*

Christopher Bentsen
Bio-Rad Laboratories
Diagnostics Group
6565 185th Avenue NE
Redmond, W A *98052*

Dear Mr. Bentsen:

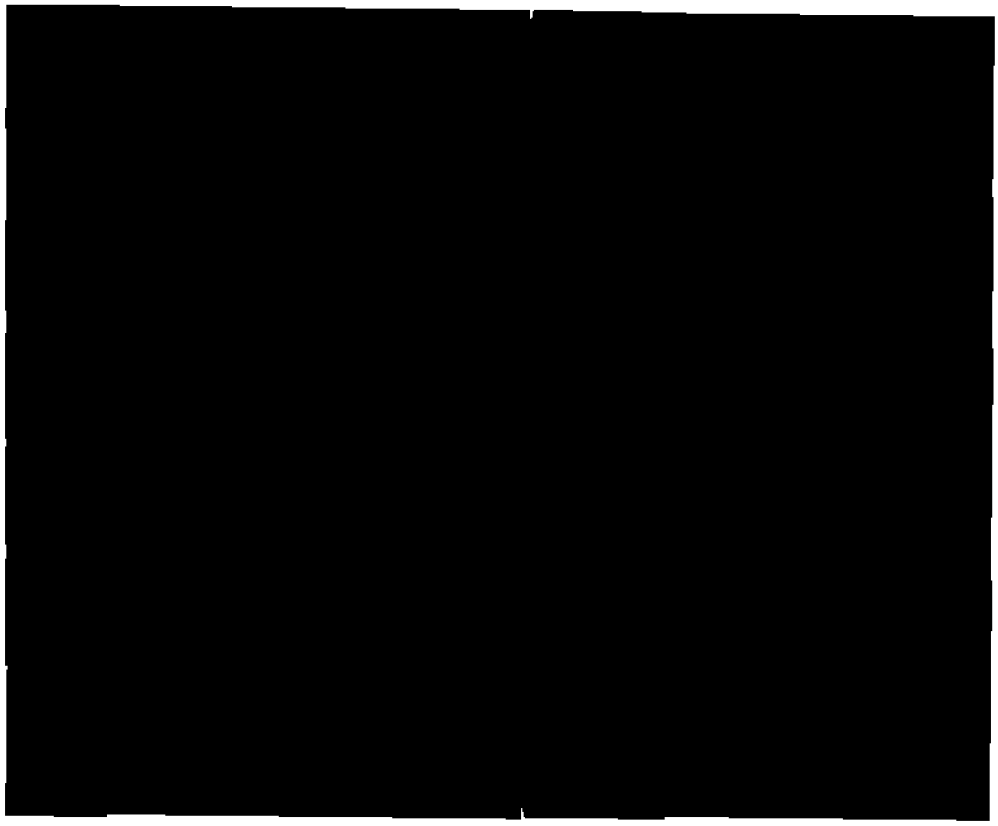
W e have approved your Biologics License Application for the Human Immunodeficiency Virus Types 1 and 2 (HIV-1 and HIV-2/Enzyme Immunoassay (EIA)/Recombinant and Synthetic) (i.e., *Genetic* Systems™ HIV-1/HIV-2 *PLUS* O EIA), a qualitative *in vitro* test for the detection of antibodies *to* the Human Immunodeficiency Virus Types 1 and 2 in human serum or plasma. Bio-Rad Laboratories is hereby authorized to introduce or deliver Genetic Systems ™ HIV-1/HIV-2 PLUS O EIA for introduction into interstate commerce, manufactured at Bio-Rad Laboratories, under Department of Health and Human Services License No.1109.

Changes to the product, production processes, location of production processes, equipment, facilities, or responsible personnel are required to be reported to FDA as specified in Title 21 Code *of* Federal Regulations (CFR) Section 601.12.

All adverse reports should be submitted according to 21 CFR Part 803 to the Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, Maryland 20847-3002. In addition, safety related information obtained in the course of other relevant clinical studies should be reported in accordance with 21 CFR 312.32. It is also requested that distribution reports be submitted according to 21 CFR 600.81.

As agreed upon in your Letter of Commitment *dater* July 14,2003 the following post-licensure commitments must be fulfilled:

[redacted]



Bio-Rad Laboratories understands that FDA reserves the right to take additional action based an the results of post market studies.

Bio-Rad Laboratories may wish to submit proposed introductory advertising and promotional campaign. If so, please submit three (3) copies of the proposed material in draft form with Part I of the FDA Form 2567/2253 to CBER, Advertising and Promotional Labeling Branch (APLB), HFM-602, 1401 Rockville Pike, Rockville, Maryland 20852-1448.

You are required to submit reports of biological product deviations in accordance with 21 CFR 600.14. All manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution, should be promptly identified and investigated. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, a report must be submitted on Form FDA.-3486 to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, HFM-600, 1401 Rockville Pike, Rockville, MD 20852-1448.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a FDF-format electronic copy as well as

original paper copies (ten for circulars and five for other labels), In addition, you m y wish to submit three draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2567 or Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2567 or Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

It is recommended that a copy of this letter be available for review at the time of FDA inspections.

Sincerely yours,

Hira L. 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