DEPARTMENT OF HEALTH & HUMAN SERVICES

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

September 18, 2001

Our STN: BL 103902

Andrew Conrad, Ph.D.
Chief Scientific Officer
National Genetics Institute
2440 S. Sepulveda Boulevard #130
Los Angeles, California 90064

Dear Dr. Conrad:

Your Biologics License Application (BLA) for the National Genetics Institute (NGI) UltraQual™ Human Immunodeficiency Virus Type 1 Reverse Transcriptase Polymerase Chain Reaction (PCR) Assay (UltraQual™ HIV-1 RT-PCR Assay) is approved effective this date. This assay, when used in combination with FDA approved pooling and resolution algorithms, is indicated for the qualitative detection of the human immunodeficiency virus type 1 (HIV-1) of ribonucleic acid (RNA) in pooled human Source Plasma comprised of equal aliquots of not more than 512 individual plasma samples. This method may be used as an alternative to currently licensed HIV-1 p24 antigen tests for screening Source Plasma. National Genetics Institute is hereby authorized to introduce or deliver for introduction into interstate commerce the UltraQual™ HIV-1 RT-PCR Assay performed at NGI's facilities under U.S. License No. 1582.

Under this authorization, you are approved to provide results of HIV-1 nucleic acid testing (NAT) of human Source Plasma pools at your Los Angeles facilities. 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 600.80 to the Center for Biologics Evaluation and Research (CBER), HFM-210, Food and Drug Administration, 1401 Rockville Pike, Rockville, Maryland 20852-1448. 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.

NGI may wish to submit any 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.

Promotional claims should be consistent with and not contrary to the approved labeling. No comparative claims or claims of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research. Final copies of advertising and promotional materials should be submitted at the time of use with Part II of FDA Form 2567/2253 to APLB. Please include copies of the approved labeling with your proposed or final copy of advertising and promotional materials submitted to CBER.

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

Sincerely yours,

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

Steven A. Masiello
Director
Office of Compliance
and Biologics Quality
Center for Biologics Evaluation
and Research