DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 1, 2011

Our STN: BL 125193/0

National Genetics Institute
Attention: Ms. Geri Cox
2440 Sepulveda Boulevard, Suite 235
Los Angeles, CA 90064-1748

Dear Ms. Cox:

We have approved your biologics license application for Hepatitis B Virus (Hepatitis B Virus/Nucleic Acid Pooled Testing/Synthetic) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Hepatitis B Virus (Hepatitis B Virus/Nucleic Acid Pooled Testing/Synthetic) under your existing Department of Health and Human Services U.S. License No. 1582. This assay, when used in combination with FDA approved pooling and resolution algorithms, is indicated for the qualitative detection of hepatitis B virus (HBV) deoxyribonucleic acid (DNA) in individual or pooled samples of human Source Plasma (or plasma samples obtained from Source Plasma donors at the time of donation). Pooled samples shall be comprised of equal aliquots of not more than 512 individual plasma samples. The Hepatitis B Virus (Hepatitis B Virus/Nucleic Acid Pooled Testing/Synthetic) is an "in-house" test performed only by National Genetics Institute.

Under this license you are approved to provide results of HBV nucleic acid testing (NAT) of individual or pooled human Source Plasma (or donor) samples at your Los Angeles, California facilities. You may label your product with the proprietary name UltraQual™ HBV PCR Assay.

We acknowledge your intention to conduct an additional voluntary study to obtain a more accurate estimate of the NAT yield in Source Plasma screening by testing at least 500,000 donations and to submit the data as a supplement within one year of the approval date of the BLA. The study will be conducted using NGI's UltraQual™ HBV PCR Assay and currently available licensed HBsAg and anti-HBc tests, and other tests as needed. The data submission will include donor IDs, accurate enumeration of positive and negative tests, Master Pool IDs, Primary Pool IDs, bleed dates, identification of donor centers that supplied all plasma samples for testing, and follow-up testing data for all NAT-positive/HBsAg negative donors.

We did not refer your application to the Blood Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues which would have benefited from an advisory committee discussion.

Please submit completed protocols showing results of all applicable tests for each manufactured lot. You may not perform tests with any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

You must submit information to your biologics license application for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, or labeling of Hepatitis B Virus (Hepatitis B Virus/Nucleic Acid Pooled Testing/Synthetic) or in the manufacturing facilities.

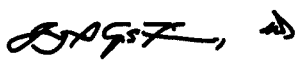
You must submit reports of biological product deviations under 21 CFR 600.14. You promptly should identify and investigate all manufacturing deviations, including those associated with processing, testing, labeling, and storage. If the deviation may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report 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 Form FDA 356h as appropriate. Please provide a PDF electronic copy as well as three original paper copies for circulars and other labels.

Two draft copies of the proposed promotional labeling may be voluntarily submitted for advisory comment with a Form FDA 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448.

You must submit adverse experience reports in accordance with the Medical Device Reporting requirements for medical devices (21 CFR 803) as required by 21 CFR 600.80(k)(2). Since your product is characterized as a device as well as a biological, submit these reports to the MedWatch System using MedWatch Reporting Form 3500A. Required reports should be submitted to the Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, Maryland 20847-3002.

Sincerely yours,



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