



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JAN 23 2003

Our STN: BL 103590/5008

Christopher Bentsen
Bio-Rad Laboratories
Diagnostic Group
6565 185th Avenue NE
Redmond, WA 98052

Dear Mr. Bentsen:

Your request to supplement your Biologics License Application for Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal) Enzyme-Linked Immunosorbent Assay (ELISA) (Antibody to HBsAg/Enzyme Immuno Assay (EIA), Version 2.0/Monoclonal) to include;

1) an additional [REDACTED] step in the manufacture of the [REDACTED] 2) changing the [REDACTED]
[REDACTED] 3) changing the Chromogen Reagent TMB concentration used from 100x to 11x, 4) use of 100 μ L sample volume instead of 200 μ L, 5) use of [REDACTED]
[REDACTED] and, 6) use of the term "Version 3.0" has been approved.

This information has been placed in your biologics license file. Please keep a copy of this letter available for review at the time of FDA inspections.

Sincerely yours,

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