DEPARTMENT OF HEALTH & HUMAN SERVICES

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

February 17, 2000

Dear Manufacturer:

This letter serves as notification of the revised requirements for the modification of product labeling nomenclature for controls and calibrators used in test kits labeled for the detection of infectious agents in blood products. The original requirements were stated in a letter by the Center for Biologics Evaluation and Research (CBER), dated November 13, 1998, to manufacturers of such products.

As revised, only new Biologics License Application (BLA) and Premarket Notification (510(k)) submissions for IVD test kits and related instrumentation labeled for use in testing blood products are required to contain the new "calibrator" and "control" naming convention. While we encourage such changes also be applied to labeling for currently licensed BLA IVDs and 510(k) products currently on the market, as well as labeling for BLA IVDs and 510(k) products that are currently pending review at CBER, they are not required to be modified at this time.

In addition, since new IVDs will likely be licensed/cleared by CBER for market before printouts and associated literature from instrumentation used in conjunction with the new IVDs will be updated to include the new "calibrator" and "control" naming convention, and in order to mitigate any confusion that may result from reading these printouts and literature, the following caution statement must be included in the package circulars of all new IVDs until all such literature and printouts have been updated:

> "This assay refers to reagents used to calculate the cutoff for assay results as [Positive and/or Negative] **"Calibrators"**. Instrument printouts and associated literature used in conjunction with this assay may refer to these reagents as **"Controls"**. ***This difference does not affect assay results.***"

If you have any questions concerning this letter, please contact Mr. Howard Balick of the Regulatory Project Management Branch, Division of Blood Applications, at 301-827-3524.

Sincerely yours,

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