DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV 13 1998

Dear

This letter is being addressed to manufacturers of in-vitro diagnostic (IVD) test kits labeled for the detection of infectious agents in blood products.

The distinction between "calibrators" and "controls" for IVD test kits labeled for the detection of infectious agents in blood products was discussed at various Blood Products Advisory Committee (BPAC) meetings (May 28, 1992, September 25-26, 1992, and December 13, 1996). These discussions involved representatives of the Food and Drug Administration (FDA), the Centers for disease Control (CDC), the Health Care Financing Administration (HCFA), and the public. As a result of these BPAC discussions which articulated Clinical Laboratory Improvement Act (CLIA) requirements regarding the use of controls in assay runs, and additional follow-up discussions on this topic among FDA, CDC, and HCFA, new Product License Application (PLA)/Biologic License Application (BLA) and Premarket Notification (510(k)) submissions for IVD test kits labeled for use in testing blood products should contain, effective the date of this letter, draft labeling reflecting the following:

1. If a reagent supplied in a test kit is used in the calculation of the cutoff, the labeled name of the reagent should contain the word "calibrator" (and should not contain the word "control").

2. If a reagent supplied in a test kit is used as a control reagent, and is not used in the calculation of the cutoff, the labeled name of the reagent should contain the word "control" (and should not contain the word "calibrator").

For PLAs/BLAs and 510(k)s that are currently pending review at CBER, please submit draft revised labeling, consistent with the above, within six (6) months of the date of this letter.

In addition, for any and all of your currently licensed IVD test kits labeled for use in testing blood products, please submit draft revised labeling, consistent with the above, within twelve (12) months of the date of this letter. For IVDs cleared under the 510(k) review process, please submit a copy of the modified labeling to CBER, within twelve (12) months of the date of this letter, upon implementation of the change.

If you have any questions concerning this requirement for accurate labeling, please contact Howard Balick, Biologics Devices Branch, Division of Blood Applications at 301-827-3524.

Sincerely yours,

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