DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 28, 1998

Our Reference Number: 95-1588

Ms. Rebecca Leaper
Cambridge Biotech Corporation
1500 E. Gude Drive
Rockville, MD 20850

Dear Ms. Leaper:

The Center for Biologics Evaluation and Research (CBER) has completed a review of your requested supplement to your product license application for Human Immunodeficiency Virus Type 1 (Western Blot) to include urine specimen testing.

Based upon the information provided to CBER, your request has been found acceptable.

You are requested to submit samples of each future master lot of the product test kit together with protocols consisting of a summary of essential manufacturing data inclusive of all applicable test results. No master lots of the product test kit shall be distributed until notification of release is received from the Director, CBER.

The expiration date of the Cambridge Biotech HIV-1 Western Blot Kit for testing urine in addition to serum and plasma cannot be later than that of the shortest dated component, including the urine controls. Considering current real time stability data, the expiration dating of the Negative Urine Control and the High Positive Urine Control is nine months, and the expiration dating of the Low Positive Urine Control is six months. Any request to extend these dating periods must be accompanied by the results of ongoing stability studies.

Any lot of Cambridge Biotech HIV-1 Western Blot Kit for urine testing found to fall outside of the approved specifications, including expiration dating periods, should be withdrawn from the market. In addition, any reports of significant product defects or product complaints concerning the use of this product should be submitted to the Office of Compliance, CBER, HFM-650.

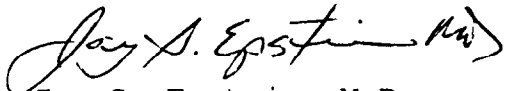
As agreed to by Cambridge Biotech Corporation, the Phase IV testing of the Cambridge Biotech HIV-1 Western Blot Kit using paired serum and urine samples in linked studies will be conducted as outlined in your Proposed Phase IV Study Protocol dated February 10, 1998, and as clarified in your letters dated May 1 and May 7, 1998.

A review of labeling has been sent under separate cover. Please submit three (3) copies of final printed labeling at the time of use and include Part II of the Transmittal of Labels and Circulars form (Form FDA-2567) with completed implementation information.

In addition, please submit three (3) copies of the proposed introductory advertising and promotional labeling. You may wish to submit the proposed material in draft form with Part I of FDA Form 2567 to CBER, Advertising and Promotional Labeling Staff (APLS), HFM-202, 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 CBER. Final copies of advertising and promotional materials should be submitted at the time of use with Part II of FDA Form 2567 to APLS. Please include copies of the approved labeling with your advertising and promotional materials.

This information will be placed on file with your product license application for Human Immunodeficiency Virus Type 1 (Western Blot).

Sincerely yours,



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