DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Bethesda, MD 20205

August 20, 1982

Ms. Marietta Carr
Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles, CA 90032

In reply refer to: HFB-200

Dear Ms. Carr:

This is to notify you that based on the review of the information included with your June 10, 1982 letter, your Source Plasma (Human) license application has been amended to include the collection of Hepatitis B antibody plasma (anti-HBs positive) from donors immunized with licensed Hepatitis B vaccine.

Please be advised that approval is for plasma to be used only for the production of Hepatitis B Immune Globulin or in-vitro diagnostics when obtained from donors with a history of hepatitis.

It is recommended that a copy of this letter be maintained on file at each location of your establishment where it may be reviewed at the time of authorized inspections.

Sincerely yours,

GRO-C

Harry M. Meyer, Jr., M.D.
Director
National Center for Drugs and Biologics

RECEIVED
AUG 26 1982
REGULATORY AFFAIRS

MDL002735