Alpha THERAPEUTIC CORPORATION
5555 Valley Boulevard, Los Angeles, CA 90032

March 15, 1983

John C. Petricciani, M.D.
Director
National Center for Drugs and Biologics
Food and Drug Administration
8800 Rockville Pike
Bethesda, MD 20205

Dear Dr. Petricciani:

As you know, media coverage of the current epidemic of Acquired Immune Deficiency Syndrome (AIDS) has included speculation that the presence of anti-HBc markers may be positively correlated with the occurrence of AIDS. Some have suggested routine anti-HBc screening of blood and plasma donors as a means of reducing the risk of contamination of blood products by the putative infectious agent of AIDS.

It is our intent to produce for test marketing purposes one or more lots of Antihemophilic Factor (Human) derived from plasma tested and found to be negative for anti-HBc. With such lots, we hope to gauge whether this product would fulfill a need within the domestic marketplace. We seek FDA's comments on this proposal.

We intend to perform anti-HBc testing on all donors (both initial and repeat) at approximately three Alpha plasmapheresis facilities. Use of more than one Alpha facility is necessary to rapidly accumulate a quantity of anti-HBc tested plasma for production purposes.

Donors found to be positive for anti-HBc will be permanently rejected as plasma donors. Any plasma collected from such donors after the positive anti-HBc result will be withheld from manufacture of non-heat treated products, i.e., Anti-hemophilic Factor (Human) and Factor IX Complex (Human). However, no action will be taken with respect to plasma units collected prior to the positive anti-HBc result.

We intend to make no promotional claims for anti-HBc negative AHF. Very soon, we will submit our proposed labeling for this product. We intend to utilize an adhesive sticker label simply indicating that the product has been derived from plasma tested and found to be negative for anti-HBc.

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In addition, we plan to revise our labeling for all Antihemophilic Factor (Human) products (including anti-HBc negative AHF) to include a cautionary statement regarding potential transmission of AIDS by blood products. Such labeling will not be initiated until FDA approval is obtained.

In light of the urgent need to address the AIDS crisis in terms of the hemophiliac population, we request the Office of Biologics' prompt review of this proposal. If further information is needed, please do not hesitate to contact me at (213) 225-2221.

Very truly yours

GRO-C

Marietta Carr
Vice President
Regulatory Affairs

cc: E. Feder
D. Gury
B. Martin
L. Johnson
B. Mealey
J. Tufekjian

MC:pw
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