Alpha THERAPEUTIC U.K. LTD.

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28 January 1988

Dear Peter,

FUTURE SUPPLY OF COMMERCIAL FACTOR VIII FROM THE U.S.A. TO U.K.

The recent conference called by the CDC in Atlanta to review issues relating to the safety of Factor VIII concentrates (after a number of HIV seroconversions occurred following the administration of 'dry' heated concentrates) also discussed the impact on future supplies of AHF for both the U.S. and overseas markets should there be a total move away from the production of 'dry' heated concentrates. These concerns were echoed during a discussion session at the recent U.K. Reference Centre Directors' meeting on AIDS held in Manchester. I have taken this opportunity therefore to outline Alpha's position and to provide an assurance that our current product, Profilate Heat treated (wet method), will continue to be made available in whatever quantity is required for as long as it is required, based on the following facts:-

1. Alpha Therapeutic Corporation supplies to-day, as they have always done, a very minor part (<5%) of the total U.S. domestic demand. Although being the largest plasma collector/fractionater in the business to-day (approx. 2 million litres in 1987) much of that plasma is sold as 'Cryo' or 'bulk intermediate' fractions within the industry, both in the U.S. and Europe.

   Finished product AHF is mainly the 'wet method' version, which is principally distributed within Western Europe, the 'dry' version having been restricted to the U.S.A. and certain other countries who preferred it on cost grounds.

2. Alpha, Armour and Travenol have now all publicly stated their policy of ceasing production of 'dry' heated AHF. Based on the points made above the impact of this decision for Alpha is minimal.

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3. The encouraging viral safety data obtained to-date on Profilate Heat treated (wet method) relative to all other 'dry' heated products that have been subjected to formal clinical study, provides us with every confidence to continue to produce this product (and to increase production if necessary given the flexibility available) until such time as superior viral safety data is available from 'virgin' studies on alternative viral inactivation and/or purification processes that would indicate a change is warranted.

4. Alpha's R & D department is proceeding with an alternative viral inactivation method, based on current generation purification techniques and material should shortly be available for clinical study. Additionally we are developing a technique for a 'high purification' Factor VIII product similar in purity to that seen with monoclonal antibody purification techniques.

In conclusion, I can also state that at present no significant (>10%) price rise is envisaged during 1988, with any price change being largely dependent on the compulsory introduction of the P24 HIV antigen test and/or HIV 2 antibody test on U.S. plasma donors and the current high level of demand for commercial material being essentially maintained in the U.K.

If I can be of any further assistance or provide you with any further information, then please do not hesitate to get in touch with me.

Yours sincerely,

I D Marshall
Marketing Director

cc: U.K. Haemophilia Reference Centre Directors