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GRO-C

22 January 1987

Dear Prof Bloom

PROFILATE HEAT-TREATED AND PROFILNINE HEAT-TREATED PRODUCED
FROM NON HIV ANTIBODY TESTED PLASMA

Heat treatment of coagulation factor concentrates was widely introduced by several companies in 1983/4 as a way of attempting to reduce and hopefully eliminate viruses such as hepatitis B, NANB hepatitis and, as it subsequently transpired the virus thought to be responsible for AIDS transmission, namely HTLV-III or HIV. Alpha's unique method of heat treatment involving heating in a suspension of n-heptane for 20 hours at 60°C (Profilate/Profilnine Heat-Treated Wet Method) was introduced to the UK in late 1984 and became the only product we offered once a total switch to heat-treated factor VIII occurred in the UK in early 1985.

Subsequently HIV antibody test kits were licensed in the USA and Alpha had fully implemented donor screening by April 1985, as an additional safeguard to the heat treatment process already in use.

Alpha has to date received no reports on HIV seroconversion in patients who have received only Profilate/Profilnine Heat-Treated (Wet Method) whether produced from non HIV tested plasma donors or HIV antibody negative donors.

Our parent company, Alpha Therapeutic Corporation has recently, in conjunction with other US manufacturers, offered to exchange any remaining inventory of lots of Profilate Heat-Treated/Profilnine Heat-Treated produced from non HIV antibody tested plasma and Alpha UK is now extending this offer to include any remaining product in the UK.

The offer is not being made because of any doubt regarding the safety of these products but in a spirit of conformity with the actions of other members of our industry and because of concern for the continued peace of mind of the potential users of our product.

Attached to this letter is a record of all batches of Profilate/Profilnine Heat-Treated that you received from us that were produced from non HIV antibody tested donors which are still currently within their dating period.

It is highly unlikely that you will have any remaining inventory of any of these lots but we would be prepared to exchange this material if it existed and if you so wished. Perhaps you could arrange to have your stocks checked and if necessary contact me in due course.

Yours sincerely/

GRO-C

I D Marshall
Marketing Director

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UNIVERSITY HOSPITAL OF WALES, CARDIFF

PROFILATE HEAT-TREATED (WET METHOD)
DRIED FACTOR VIII FRACTION BP

| <u>LOT NO</u> | <u>ASSAY</u> | <u>EXPIRY DATE</u> | <u>TOTAL QUANTITY DISTRIBUTED (VIALS)</u> | <u>PERIOD OF DISTRIBUTION</u> |
|---------------|--------------|--------------------|---|-----------------------------------|
| A6-0560 | 1000 | 7.3.87 | 140 | Apr 85-Jun 85 |
| A6-0650 | 1010 | 16.4.87 | 310 | Jun 85-Jul 85 |
| A6-0740A | 510 | 28.5.87 | 167 | Aug 85-Oct 85 |

PROFILNINE HEAT-TREATED (WET METHOD)
FACTOR IX COMPLEX

| <u>LOT NO</u> | <u>ASSAY</u> | <u>EXPIRY DATE</u> | <u>TOTAL QUANTITY DISTRIBUTED (VIALS)</u> | <u>PERIOD OF DISTRIBUTION</u> |
|---------------|--------------|--------------------|---|-----------------------------------|
| B2-0060 | 510 | 25.3.87 | 300 | Jun 85 |
| B2-0080 | 510 | 24.4.87 | 465 | Aug 85-Oct 85 |
| B2-0120 | 520 | 25.6.87 | 100 | Oct 85 |

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