Confidential

MILES Stoke Court

Date 21st January 1986.

Copy To

To B.A. Dyos

From M.W. Tatt

Subject YOUR VISIT TO U.S.A.

The following information on Konyne-HT is urgently required for our submission to the CSM. We cannot make arrangements for the hearing until the data are assembled and the commentaries written up for inclusion in our representation.

1. A commentary on the results of the studies included in the P.L. application entitled "Virus Inactivation Kinetics in Dry Heat-Treated Factor IX Complex (Human)" and "Inactivation Kinetics of Sindbis Virus and Feline Leukaemia Virus in Dry Heat-Treated Factor IX Complex (Human)".

2. An overall discussion of these results and other studies which were carried out to demonstrate that the heating process is effective in preventing transmission of infectious viruses.

   What can we conclude from these studies apart from the fact that HTLV III/LAV is inactivated?

3. Any clinical data which have recently become available particularly with reference to NANB hepatitis. Are they monitoring clinical use in any country?

4. Do we claim that our dry heat-treatment process is as good as any wet heat-treatment process in reducing the risk of transmitting NANB hepatitis? If so, what reasons do we give for making that claim? If not, what reasons do we give for employing dry heat-treatment?

Brian, this representation needs to be prepared very carefully if we wish to obtain a product licence in the U.K. I think we could get a licence if we address the questions raised by the CSM in the correct manner.

Would you ask Cutter U.S.A. what they are doing to help us? Also, are they going to introduce ALT testing of donors.

Regards,

GRO-C

Marie.
MWT/svs

118 4553

MIL 111039