Interoffice Communication

MILES

FAX - BERKELEY

Cutter Laboratories
STOKE COURT

Date: 29 September 1987

To: Dr R Rousell

From: Marie W Tatt

Subject: KONYNE HT - EXPERT REPORT

Copy to: B A Dyos
E Greene
C Moore
Dr J Pennington

Our KONYNE HT PLA was submitted two years ago but the CSM required further information on safety and efficacy before recommending the grant of a product licence. After discussion with the licensing authority it was agreed that we would have to provide some long term evidence of safety in clinical use with special reference to the transmission of infectious viruses. The question of efficacy is less of a problem.

After further discussion with the licensing authority on the problems of generating the safety data we decided to approach a haemophilia centre director in the UK to obtain support for our submission to the CSM. Unfortunately, we have not yet been able to find anyone willing to do this, although Professor Temperley had indicated to me that he would be prepared to assist us.

The CSM is now pressing us for a response to their request and we need to do something before the end of this year.

We still wish to register KONYNE HT in the UK and I feel that we should be able to provide a satisfactory response to the CSM with or without the support of a UK clinician. At least we could make a stab at it.

There was not sufficient time to discuss this submission in detail during my recent visit to Berkeley, but I would like to talk with you and Eli about it as soon as possible. If you could spare some time to meet me during your next visit to the UK I would be grateful. By copy of this memo, I would like to ask Eli if he is planning a visit to Europe in the near future and could manage to meet with me.

Regards,

GRO-C

Marie Tatt

Cutter