Mr. D. W. WAIN .

SUMMARY OF MEETING AT D.H.S.S. 2ND JUNE 1983

PARTICIPANTS

Dr. K. Fowler
Dr. J. Purves
Anne Walton
Sarah Middleton

SUBJECT

Clinical trials certificate for Mono VIII:C - source of cryoprecipitate.

1. Dr. Fowler was of the opinion that, despite the controversy surrounding US imports as a result of AIDS, our application will not be judged prejudicially by the CSM if we pursue it with Alpha cryo cited as source material. There have been suggestions in certain quarters about the banning of importation of all US blood products but the impracticality of this is recognised by those who are well informed in this area and a ban does not, therefore seem likely. An application based on Alpha cryo would (or should) be judged solely on its scientific merit.

2. The possibility of leaving an application open-ended with respect to source material was discussed and dismissed as unacceptable.

3. We were advised that, if a change in source material is desired, the application might proceed more easily if the licensing of the import of the cryo were included in the CTC application. The responsibility for the quality of the raw material would then be entirely Speywood's and in addition, the cryo would then be licensed for importation only for the purpose covered by the CTC.

POSSIBLE COURSES OF ACTION

1. Proceed with the application citing Alpha cryo as source material

   We were advised that, if this is to be done, it would be advantageous to ask for a hearing since this gives the opportunity of making written representation and in addition of answering further questions in person. If a CTC is granted for Mono VIII:C from Alpha cryo we can then either
   a) Procced using this cryo or
   b) Request an alteration to another cryo before commencing trials.

2. Change the source material cited

   In this case it would be advantageous to withdraw the application and re-apply when a new source is defined. An advantage of this course of action is that we have the opportunity to re-assess the data so far submitted and possibly avert certain questions at Product Licence stage.

   A disadvantage is the fact that the questions so far asked of us under the 21(1) letter we received are quite basic and straightforward. A re-application would give the committee the chance to re-think the data and might result in our having more difficult questions to answer at the CTC stage.

In conclusion it appears that the use of US cryo will not prejudice our case with the licensing authorities and therefore our choice of source material can be based on commercial and scientific grounds.

EAW/JUNE '83