Telephone conversation PAG/CB/Anita Bessler 28.2.86 **U0000043**

Report of meeting held in Fort Washington to discuss Factorate on 27.2.86 as follows:-

Those present:
Dr J Tretter
Mr B Dovey
Mr R Cawthorn
Dr M Rodell
Dr K Hansen
Mr S Samuels
Mr J Cedor
Joe Smith
Anita Bessler
Mr J Miller
Dr Terry (via telephone)

Reviewed the technical data available from Meloy and from Erlich Institute and all the other sources.

The meeting then reviewed on a case by case basis every instance of sero-conversion that has been reported anywhere in the world - this information gathered from US, UK and other subsidiaries - only subsidiary that responded was UK so assume there have been no other reports except from UK. Also reviewed the information that Mike Rodell had obtained from talking to the Office of Biologics - a lot of discussion took place. The net result of these discussions was that, in the opinion of everyone at the meeting, there is no problem with Factorate drawn from unscreened donors. However, it was felt that, just as with any ongoing improvements which have been made with Factorate, adding the screening to the donor pool is an improvement to the product and we should, first of all, withhold from distribution all non-screened product, under one stipulation. This is that, withholding that non-screened product does not result in patients being unable to obtain a product or the potency they want when they order, or hospitals or physicians not being able to have access to the particular product that they have designated for the use of specific patients.

In other words, the meeting felt that there no reason to believe there was a problem with non-screened product but, at least in theory, by screening, we will improve the product even more and we should do as much as we can to implement these improvements as quickly as possible.

In the meantime, it was considered there was no reason to cause any problems in terms of the normal day to day delivery of Factorate to our customers, etc. based on all the information available to date. In terms of the US and UK and everybody else who has non-screened product in inventory, we will continue to withhold the distribution of that product as long as, or unless, we only have that type of product to distribute within the market. In other words, it is a voluntary withholding and not a withdrawal from the market. As far as Scandinavia is concerned, the same thing will happen there, with the exception of Nilsson, who has requested that she use only screened material in future.

The meeting agreed that it was very important to gear up production in Kankakee and to, as rapidly as possible, be in the position where not only will we not be distributing product from non-screened donors but that we will reach a point where, without interrupting the supply to the patient, we can exchange un-screened product with material that has already been screened.

PAH/LEW
28.2.86

cc: Mr R Christie
Mr C Bishop