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17th October 1989
PJC/BMC

Mrs. I. Diernhofer,
Immuno AG,
Industriestrasse 72,
A1220 Vienna.

Dear Mrs. Diernhofer,

I was very disappointed to hear from Mr. Nicholson that we are still experiencing delays in preparing the registration data for Kryobulin, Feiba and Prothromplex.

As you are aware, we are now in the third year since our meeting at the Ministry when it was established what data would be required. We have been promised completion dates for the data on numerous occasions. As I have already mentioned in previous letters, the submissions for these products continue to be a great embarrassment for our company, both in our relationship with the Department of Health and our principal customers.

We appreciate that Professor Woeber have been having problems in producing the data concerning validation of production, but I think we are now at the stage when we should submit the data we have in hand irrespective of whether the validation data is available. We feel that we cannot wait any longer and we must submit our applications in order to 'join the queue' of Product Licence Applications awaiting assessment. Once we have done this we can continue with the validation data and submit this at a later stage if it is required.

We must remember that the situation has changed slightly in that we now have a vapour heated product licensed and these new applications may be reviewed more favourably.

During discussions with Dr. Schwarz earlier in the year we all agreed on the date of July this year and then it was postponed to October. We are obviously not going to meet this deadline. Could we please, therefore, agree to a new date for these 3 applications.

I understand from Mr. Berry that he has discussed with Dr. Schwarz the question of amending the Irish Tisseel Licence to vapour treated and it was agreed that this could be prepared for submission.

The UK Product Licence Application for vapour treated Tisseel is obviously very important for us and we must submit this as soon as possible. You are aware that we have in principle decided to change to human thrombin, but Mr. Nicholson and I feel that this could delay the application for some considerable time.

We would, therefore, like to suggest that we submit a steam treated Tisseel application in the UK using bovine thrombin whilst the licence is being processed. This will enable us to 'join the queue' whilst our licence is being considered and we carry out the work that is required on the human thrombin.

Fells uses same step

Once again, we thank you for your efforts on our behalf concerning the registration in the UK and I look forward to receiving your comments on the points I have raised.

Kind regards,

Yours sincerely,
for IMMUNO LTD.

GRO-C

P.J. Coombes
Managing Director

cc Dr. O.F. Schwarz