Baxter

Interoffice Memorandum – For Internal Use Only

To: David Galliford - Thetford

c.c. Tomye Tierney - Glendale

Date: 22 May 1990

From: Andrew Whitaker

RECEIVED
23 MAY 1990
Ans'd.....

DR LANE VISIT TO HYLAND

David,

Now that we have a Letter of Intent agreed with BPL, Dr Lane urgently wants to visit Hyland to review our licence submissions for both Gammagard and Hemofil M.

Dr Lane's objectives are to satisfy himself that we are able to demonstrate safety and efficacy for both products, to estimate the time to licence approval and to assure himself that gaining the product licences will not be problematic - he is aware that we have had problems demonstrating viral safety on Gammagard to the Department of Health's satisfaction. Since he has been involved in the licencing process and since BPL still enjoys crown immunity, he is also keen to offer any suggestions and/or help that would speed up the process to our mutual benefit - could BPL, for example, submit our data and using their special status get product licences registered more quickly?

On the Gammagard front, it is important that we are able to explain the cause of the delays, and present a clear action plan with timings and responsibilities of what we now have to do, together with an indication or opinion from the Department of Health that this plan meets their requirements. Could you ensure that this is put in place please?

In view of the proposed programme, should Ivan be attending the Hyland meeting with Dr Lane? If not, could you ensure that you/Ivan are able to discuss with the appropriate Hyland personnel exactly what will be shared with Dr Lane and that the UK Regulatory Group has had the opportunity to make its imput. One particular question that has been raised relates to the delay in submitting the Gammagard filing (see attached note from Tomye Tierney). Could you respond to Tomye please and copy me in.

Many thanks

GRO-C

Andrew Whitaker
Business Manager

VJB/495

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