Dear Charles,

IN VIVO TESTING OF FACTOR VIII CONCENTRATE

Following our telephone conversation yesterday I enclose, for your information, a copy of table 3.8 extracted from our application for a product licence for Human Antihaemophilic Factor. This table gives you a summary of all of the parameters which we require to satisfy for approval by the Medicines Commission and by the National Institute of Biological Standards and Control.

At the time that we applied for a product licence the BP requirement for pyrogen test was that we inject 3 ml/kg of rabbit but, subsequent to this, the test dose has been modified to provide a minimum of 10 IU/kg of rabbit. This is in keeping with the new European Pharmacopoeia requirements and has been agreed as a variation by NIBSC. Further agreement is not required from the Medicines Commission at the present time since the original reference (9.70) contained a caveat that the test dose would be such as might be stipulated by the European Pharmacopoeia from time to time.

I enclose also batch summary sheets for batch numbers 430 and 434. I have also arranged that samples from these batches should be dispatched to you.

You will notice from the summary sheets that both batches meet the requirements of the licence in all circumstances but that in both cases the pyrogen test result is at or close to the limit. However, you may care to note also that the limulus test for batch 430 showed a clear pass in the neat solution whereas that of 434 passed at a 1:50 dilution whereas the limit specified and accepted for the licence is a pass at 1:100 dilution. From past experience on the basis of the limulus test alone I would be happy to issue both these batches for clinical use but, at the same time, respect/
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Regional Director - jgw.imm 2.167/2  

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respect Miss Patterson's desire that the products have some clinical experience under controlled circumstances before they are exposed to general issue. The substance of her concern is primarily that these products are increasingly issued for use in home therapy programmes where medical supervision and reassurance is less readily available.

Miss Patterson is most grateful for your kind acceptance of the task of introducing these batches to clinical experience and will be grateful for your report in due course.

With much thanks and kindest regards.

Yours sincerely


JOHN G WATT  
Scientific Director

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