

Our Ref: DRW/GC

20th May 1982

Dr. B. Noel,
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France.

Dear Dr. Noel,

Very many thanks for your April 16th letter. My apologies for the delay in replying, but as usual, I am hardly ever in the office.

I am extremely sorry that we have been out of touch for so long, but as you know, Speywood is still a very small company. It is totally impossible for us to pursue all our interests and potential collaborations at the same time.

I was very interested by your proposal. Progress with development of the polyelectrolyte technology for producing high purity human factor VIII:C has been much slower than we hoped. However, we are starting production of pilot-scale quantities for clinical trial in our own unit during the next month. Initially, supplies will be very restricted and it will be into 1983 before we have capacity to produce commercial quantities. The preliminary laboratory and clinical evidence which we already have makes it clear that the product will be of tremendous benefit.

There are three major advantages with this material. Protein content is very low, with around 10 units of factor VIII:C activity per milligram. There are no ~~isoelectric points~~ ^{isoelectric points}. Of major interest is the in-vitro evidence of lack of hepatitis B infectivity. Of course, this latter point can only be proven in patients with clean livers. One of the clinical studies planned in the U.K. will address this point.

Starting with cryoprecipitate, we are now regularly obtaining yields of 30% of the starting activity. Whilst this is commercially satisfactory, for an organisation such as your own, it does represent a significant loss of factor VIII availability. Even given the advantages of our product, I would thus be surprised if you were prepared to commit your total cryoprecipitate collection to the polyelectrolyte process.

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