Our Ref: DRW/GC 21st October 1982

Mr. J. Sloggam,
Room 717,
Scientific & Technical Branch,
D.H.S.S.,
14 Russell Square,
London,
WC1B 5EP.

Dear John,

Having failed to reach you by telephone during the past few weeks, I thought I would drop you a note, as I am out of the office again until early November.

Following your last meeting with my colleagues in Wrexham, I wanted to up-date you with the regulatory position concerning Hyate:C. Although we are now moving ahead with clinical trials and product licence applications in various overseas countries, we have not yet progressed in the U.K.

The reason for this, is the apparent insistence by Medicines Division, that we compare the product against an established, registered, alternative form of therapy. As you know, the only registered product for the treatment of haemophilia A, are human factor VIII preparations. As these are contra indicated in the patient population which we are addressing, it is just not practical to mount a trial of the required nature. Apart from anything else, the clinicians would refuse to participate.

We are also confronted with another problem outside our control during the next year or so. This is the Autoplex study, which I believe has now started and, which takes many of our potential patients.

Having considered ~~this~~this afresh during the past few weeks, I have now decided to go straight for a Product Licence, with a target date for submission of our data by the end of this year. Whether this will fly or not, it will certainly give rise to some questions and open meaningful discussions.

/contd.....

Mr. J. Sloggam 21st October 1982

/contd....

I will be back in the office on November 1st, if you would like further information.

Yours sincerely,

David R. Williams