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27 April 1984

Dr J D Cash
National Medical Director
Headquarters Unit
SNBTS
21 Ellen's Glen
EDINBURGH

Dear John

HEAT TREATED FACTOR VIII

We have delineated a timetable for the manufacture of Heat Treated FVIII and we are, at the present time, on schedule. The first batch is now ready for issue but only amounts to 30 vials @ 100 IU available for issue. Our expectation for the future is to make available at least 100 vials @ 200 IU per month starting in May. I believe the time has now come to begin to construct a formal clinical trial of this product with a view to submission of a formal licence application in 1985 and I would welcome your views on how best to proceed. A major consideration from the PFC point of view is to establish whether the trial is conditioned by PFC's production capacity for this product or more sensibly, that PFC implements a production schedule to meet the defined needs of a comprehensive trial. The latter should be the chosen course of action and will require the appointment of a trial co-ordinator who will ultimately carry responsibility for presenting the clinical trial data (experience of IgG trial).

In the meantime preliminary construction of the pharmaceutical component of the licence application is underway which should, if at all possible, be synchronished and compatible with the clinical evaluation.

Perhaps we can discuss this on May 2nd but in any event I would welcome your views.

With kind regards.

Yours sincerely

R J PERRY
Director (Acting)