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15th July, 1986

Director,
Dr. R. J. Perry

REF: pf.w. 2.46
WP REF: HPLC/F8.

Dr. J. Dawes
H.Q. Laboratory
2 Forrest Road
EDINBURGH

Dear Joan,

HPLC STUDIES ON HEATED FVIII

Here are some vials of our new (phase III) FVIII concentrate from our first pre-production batch. Two vials are unheated (blue label) and two have been heated at 80 °C for 72h (red label). The product has been designed to be reconstituted in 20ml. This will give 10.6 iu/ml (unheated) and 9.0 iu/ml (heated), total protein 27.4 g/l.

Duncan has asked for 6 unheated vials, can you tell him that he hasn't been forgotten and that we will be putting material aside for him from the next batch (scheduled 28th July).

The composition of the cryoprecipitate for the NY lots you have studied is as follows:-

| NY Lot | Cryo Wt g/l plasma | Protein g/l plasma | FVIII Content iu/mg protein |
|---------------|---------------------------------------|-----------------------|--------------------------------|
| 5032 (18h) | 12.04 | 1.21 | 0.273 |
| 5037 | 12.18 | 1.32 | 0.280 |
| 5044 | 12.62 | 1.69 | 0.257 |
| 5054 | 12.25 | 1.39 | 0.322 |
| 5055 6/18 | <i>still trying to find the data.</i> | | |
| 5058 (18h) | 13.08 | 1.27 | 0.279 |
| 5063 | cryoppt frozen in centrifuge | | |
| 5065 | 13.17 | 1.70 | 0.219 |
| 5066 | <i>still trying to find the data.</i> | | |
| 5067 (18h) | 14.25 | 1.70 | 0.195 |
| Range 1984-86 | 7.2 - 16.7 | 0.91 - 1.77 | |

The cryo wt for these lots is much higher than we were seeing in 1973/74 ie the data I recently copied to you from the 6h/18h comparison. This increase seems to

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have taken place during 1985 (see graph enclosed) and I suggest that it is probably due to a number of changes that were made to our plasma conditioning room at this time. i.e. The plasma may now be slightly too warm prior to crushing and thawing. I would anticipate that some fine tuning with this temperature should take us back to 1984 quality (ie 9.0 g cryo/l plasma).

Best wishes.

Yours sincerely,

GRO-C

PETER R. FOSTER