



Assuring the quality of biological medicines

Blanche Lane
South Mimms
Potters Bar
Hertfordshire EN6 3QG
United Kingdom

F A X

15 November 1995

Mrs Glenda Silvester
Department of Health
Medicines Control Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Dear Glenda

Re: BPL 8Y

We are currently "in dispute" with BPL on a batch of 8Y, No FHB 4443, where our potency estimates after repeat assays average 70% of the labelled value (Table enclosed). BPL have also done repeat assays and investigated their production records and do not wish to relabel at a lower potency. We both use the same standard (British Working Standard FVIII Concentrate) and assay method (two-stage) so this difference is hard to understand, but it comes against a background of a trend towards lower potencies in NIBSC assays of 8Y in the last few months, as can be seen in the enclosed Cu-Sum analysis.

BPL have agreed to send samples to a third laboratory for independent testing and we are arranging a meeting with BPL to discuss the reasons for the discrepancies. In the meantime there is apparently an urgent clinical need for this dosage form of 8Y and Terry Snape will be contacting you soon about this. Whilst I have no wish to hold up supply of clinically essential material I do not feel I can sign a batch release certificate at present on the basis of the data we have.

Yours sincerely

GRO-C

CP Trevor W Barrowcliffe
Head, Division of Haematology

To	MRS G SILVESTER	
Company		
From	T BARROWCLIFFE	
Company		
Tel No.	No. of Pages	2
		Ref No: 7686

FAX
Post-It Fax Note

National Institute for Biological Standards and Control

Telephone 01707 654753 Fax 01707 646730 Telex 21911 Nibsac G

A World Health Organization International Laboratory for Biological Standards

NIBSC Potency Estimates on BPL 8Y, Batch FHB 4443
(Labelled 465 IU/vial)

Vial No	Assay No	Potency IU/vial	
		British Standard	EP Standard
1	1	342	342
	2	324	324
2	1	338	322
	2	320	340
3	1	320	326
	2	318	334
	Mean	326	332
% of Label		70	71

Both British and EP Concentrate Standards were incorporated into the same assays.

Cu-sum analysis of potency estimates of FVIII concentrates

