



PROTEIN FRACTIONATION CENTRE

Our Ref: BC/DMAL/ 1

12 May 1992

Dr R J Perry
Director
Protein Fractionation Centre
EDINBURGH

16/25

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Dear Dr Perry

SECURITY OF PLASMA FROM NORTHERN
IRELAND BLOOD TRANSFUSION SERVICE

As you know, the SNBTS Quality Audit programme was established primarily to provide documentary evidence that the SNBTS plasma specification is being complied with by each RTC. A formal commitment was made to the Medicines Inspector that this type of supplier audit would be carried out and action taken to rectify identified deficiencies. This is a clear obligation defined in the EEC Guide to Good Manufacturing Practice and is implicit in EEC Directives 89/381/EEC and 91/507/EEC.

The first audit of Belfast RTC took place on 20-22 November 1991 and revealed a significant number of serious quality deficiencies relating to plasma processing and testing procedures. I consider that these deficiencies are so serious that there is a significant risk of non-compliant plasma being dispatched to PFC. For this reason, a brief summary was produced by Dr Reid and myself, (dated 18/12/91) which listed all of the deficiencies which need to be rectified if our plasma supply is to be considered secure. A suggested deadline of 30/06/92 was established. Two audit follow-up trips have now been made by the audit team and it is the view of Dr Reid and Mr Bruce that this deadline will not be met.

I believe that we are obliged as licensed manufacturers to take formal action in order to secure the safety of our raw materials and to ensure that all RTC's comply fully with our current plasma specification. We must, therefore, take urgent measures to ensure that the deficiencies detected in the NIBTS audit are rectified. I would, therefore, suggest that we should urgently raise this matter with NIBTS and agree a date during 1992, by which time all of the deficiencies relating to PFC/.....

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plasma collection, testing and processing will be rectified. I would advise that, in my opinion, any failure to meet this agreed deadline should result in the discontinuation of fractionation of NIBTS plasma, until we are assured that the deficiencies have been rectified.

The NIBTS is a valued customer of the SNBTS and I believe that we should make every effort to assist them in overcoming the quality deficiencies. I would, therefore, propose that the PFC Quality Team offers every assistance in ensuring that NIBTS can meet the agreed target. I would offer my personal services in co-ordinating this exercise with the following elements:

- Assist in providing GMP training.
- Assist in designing suitable documentation systems.
- Assist in appointing a GMP consultant to NIBTS, who will assist in co-ordinating the generation of the necessary documentation and systems.

I would welcome your response to the contents of this letter.

Yours sincerely

GRO-C

DR B CUTHBERTSON
Quality Manager

✓ cc Prof J Cash
Mr D McIntosh