

29 MAY 1992



NATIONAL SCIENCE LABORATORY

CVP/LG

26th May 1992

Dr R Lane
Bioproducts Laboratory
Dagger Lane
ELSTREE
WD6 3BX

Dear Richard

VIRALLY INACTIVATED PLASMA

Thank you for the draft of the agreement. I hope you received my fax with preliminary comments.

Our lawyers have now looked at this and I enclose a copy of the draft with their proposed amendments written on. In addition I would comment:

- a) As agreed, we will require a letter or agreement on supply and liability matters, between CBLA and SNBTS.
- b) We will need to provide you with details of the virus testing kits (Abbott) currently in use at Glasgow BTS. You should note that they use CP2D anticoagulant (not on your list in the specification, but same citrate content as some of these - see clauses 4.8 & 4.9).
- c) An appropriate mechanism for transfer of donation numbers will need to be devised, if the computer approach outlined at clause 8.3 of Annex 1 is not feasible between SNBTS and CBLA. It seems likely we will be using paper documentation.
- d) I hope that clauses 6.2 and 6.3 are seen by Octapharma as sufficient commitment to clinical trial and CTX application.

Letters a:22059202

Blood Transfusion Service
Department of Transfusion Medicine
Royal Infirmary, Lauriston Place, Edinburgh EH3 9HB
Tel: 031-229 2585 Fax: 031-229 1069

BPLL0003518_0001

- e) The reference to clause 6.9, which does not exist, in clause 6.6 can presumably be omitted as the section in parenthesis appears to add nothing and the residual clause seems adequate (with the proviso that I presume HCV ELISA repeat positive (but unconfirmed) donations are not acceptable).
- f) I would be grateful if you would pass the enclosed copies of Lorna Williamson's product insert and label, on which we have made some suggestions, to Andrew West-Watson.
- g) I look forward to receiving Annexes 2,3,4 and 5 and would appreciate sight of the document after redrafting in the light of your own lawyers views and the enclosed.

I understand that on 14th May Lille CRTS provided documentation of their process to A West-Watson. I would appreciate a copy of these (SNBTS have, as T Burnouf can confirm, signed a confidentiality agreement on VIP with Lille). Assuming this is of appropriate quality, my understanding is that we would then set in place a parallel trial of the Lille product, involving 3 further RTC's. Can you confirm?

Yours sincerely

GRO-C

Dr C Prowse
Director NSL

Enc

Copy to: Prof J Cash
Mr D McIntosh
Dr L Williamson

PS: Glasgow have assembled the appropriate plasma pools and documentation (all rhesus positive, group A and O segregated). Could you send us the appropriate BPL dispatch forms, if necessary?

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