DEPARTMENT OF HEALTH & SOCIAL SECURITY
Alexander Fleming House, Elephant & Castle, London SE1 6BY
Telephone 01-407 5522 ext GRO-C

1 August 1986

Dr Richard Lane
Blood Products Laboratory
Dagger Lane
Elstree
Borehamwood
Herts WD6 3

BC papers
Untested plasma.

Dear Dr Lan

As you are ble recent
publicity r d plasma for
Factor VIII IX production.

In defending this usage you have relied on the rigorous heat treatment given to these products, a position which we have supported. However, the difference between your own practices and those adopted by commercial companies which are bound by the Medicines Act has drawn attention to your position outside the Act. It is therefore essential that BPL should be subject to some external safeguard for public reassurance and I would therefore ask that you submit all batches of Factor VIII and Factor IX to the National Institute of Biological Standards and Control for HIV antibody testing as part of your product release procedures in the future.

It also seems timely that you begin a dialogue with Medicines Division to work toward the preparation of information required for applications for Clinical Trial Certificates, Product and Manufacturing Licences. It has been the policy of successive Secretaries of State from Sir Keith Joseph onwards to require manufacture within the NHS to conform to the same standards as would be required for commercial firms.

Yours sincerely,

GRO-C

E L Harris
Deputy Chief Medical Officer

67/1.

7 AUG 1986

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1 August 1986

Dr Richard Lane
Blood Products Laboratory
Dagger Lane
Elstree
Borehamwood
Herts WD6 3BX

Dear Dr Lane

As you are aware there has been considerable recent publicity regarding your use of unscreened plasma for Factor VIII and Factor IX production.

In defending this usage you have relied on the rigorous heat treatment given to these products, a position which we have supported. However, the difference between your own practices and those adopted by commercial companies which are bound by the Medicines Act has drawn attention to your position outside the Act. It is therefore essential that BPL should be subject to some external safeguard for public reassurance and I would therefore ask that you submit all batches of Factor VIII and Factor IX to the National Institute of Biological Standards and Control for HIV antibody testing as part of your product release procedures in the future.

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