Baxter Healthcare Ltd.
Caxton Way, Thetford
Norfolk IP24 3SE
Great Britain

Telephone: Thetford (0842) 754581
Telex. 81319
Fax: 0842 752219

RECEIVED
03 JAN 1991
Ans'd.....

Baxter

DG

January 3 1991

Mr. L.R. Whitbread,
Assistant Secretary to CSM,
Market Towers,
1, Nine Elms Lane,
London,
SW8 5NQ.

Dear Sir,

Re: HIV-2 Testing Of Blood Donors

Please accept our apologies for the delay in formally responding to your letter of 21st June 1990.

Our Hyland Division will institute HIV-2 testing of plasma units using the combined HIV-1, HIV-2 test kits currently awaiting FDA approval. This testing should be initiated by mid 1991, dependant on FDA approval and the estimated 6-8 weeks necessary to qualify the test for use in our screening laboratories. No further batches of licenced product will be submitted to the NIBSC for batch release until this testing has been introduced.

Current clinical trial batches of Gammagard IGIV and 20% Buminate (Albumin) made using non-HIV-2-tested donations will continue to be used until exhausted.

Should you need any further information concerning Hyland's plans do not hesitate to contact me.

Yours sincerely,

GRO-C

Ivan J. Bryant
Senior Regulatory Officer

Registered Office as above
Registered in England No. 461365

SHPL0000293_044_0001