Dr. R. D. Andrews,
Senior Medical Officer,
Department of Health and Social Security,
Medicines Division,
Finsbury Square House,
33-37a Finsbury Square,
London E.C.2.

4 March 1976 JB/jm

Dear Dr. Andrews,

Anti-Haemophilic Factor (Human) Koate - PL/0010/0061

Further to my letter of 27 February, and my telephone call to you last Monday, I am now enclosing the reply which we had from Cutter in answer to questions 4 & 5 of your Section 44 letter. I am afraid that I rather anticipated their answer in my previous letter. As you can see from the enclosed, they do not collect information about the rejection of donors, but the collection of plasma is carried out according to the U.S. Code of Federal Regulations. With regard to the imposition on batch release procedure, they are not in complete agreement with it. However, as you can see from their comments, it is only certain aspects such as the provision of samples of Koate which they object to, but are quite willing to provide complete summaries of all testing performed on Koate prior to release on a lot by lot basis.

I trust that the Licensing Authority will now be able to continue the assessment of our application for a product licence.

Yours sincerely,

Mrs. J. Bount, B.Pharm, M.P.S.,
Registration Officer.