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**Department of Health and Social Security**

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GRO-C

Mrs J M Boulton, BPharm MPS  
Registration Officer  
Bayer UK Limited  
Pharmaceutical Division  
Haywards Heath  
West Sussex RH16 1TP

Your reference

Our reference

Date

7 May 1976

Dear Mrs Boulton

PL/0010/0061

12 MAY 1976

Thank you for your letter of 23 April 1976 which I have discussed with Dr Bangham. Your letters of 20 & 23 April do not constitute an adequate reply to the section 44 letter of 11 March.

It will be necessary for this letter to be answered satisfactorily point by point in detail before the licence can be reconsidered. Cutter may not be aware of the extent to which control of Factor VIII products imported into this country has had to be upgraded.

Dr Bangham has kindly offered to explain the quality control difficulties if you should wish to send someone to NIBSC Hampstead.

Yours sincerely

GRO-C

R D Andrews  
Senior Medical Officer