



Medical Research Council

National Institute for Biological  
Standards and Control

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DRB/ML/76/082C

18th March 1976

CONFIDENTIAL

Dr R D Andrews  
Senior Medical Officer  
Department of Health and  
Social Security  
Medicines Division  
Finsbury Square House  
33-37a Finsbury Square  
LONDON EC2



Dear Dr Andrews

Antihaemophilic Factor, Koate  
Bayer-Cutter  
PL/0010/0061

I return herewith the letter addressed to you from Mrs J Boulton of Bayer UK Ltd dated 4th March 1976 in which the firm objects to the batch release system for their product.

I would not agree to the licencing of this product unless Batch release for this product is implemented.

Experience with all such products so far licenced has revealed deficiencies in proper formulation of information on protocols, as well as unacceptable assay biometry and methods.

Yours sincerely

GRO-C

D R Bangham  
Head: Division of Hormones and Blood Products

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