

REF: DH/jem

15th October, 1976.

Dept of Health & Social Security,  
Medicines Division,  
Finsbury House,  
33-37a Finsbury Square,  
London  
EC2A 1PP.

Dear Sir,

Product Licence No 3070/0004 Koāte - Application for label  
variation:

I enclose copies of proposed new bottle label, carton and pack  
leaflet for the above product-Koāte.

In essence the label and carton have been redesigned to  
incorporate the labelling requirement of the Antihaemophilic  
Fraction B.P. which were not included on the American pack

i.e. 'administer immediately'

'warm to 20° - 25°C.'

'reject if a gel forms.'

'full electrolyte disclosure'

and of course Speywoods name and licence number.

The pack leaflet has been Anglisised and the hepatitis warning brought  
in line with declarations made by competitive products.

I trust these meet with your approval, and look forward to an  
early communication.

Yours sincerely,

David Heath