New File C.S.M - HPF Back up Information FILE

SGB/JH 20th November, 1978

Department of Health and Social Security,
Finsbury Square House,
33/37a Finsbury Square,
LONDON,
EC2A 1PP

Dear Sir,

APPLICATION FOR PRODUCT LICENCE FOR HIGH POTENCY FACTORATE

Please find enclosed six copies of Volume I and II of our Submission for a Product Licence for a new high potency form of Factor VIII, to be identified as High Potency Factorate. This product has been developed to meet the demands of increased, unitage of the anti-haemophilic factor and to eliminate the need for manipulating multiple vials with attendant sterility problems.

Reference to our previous submission, namely Antihaemophilic Factor B.P. (Factorate) PL 0231/0038, will confirm that we have examined this product for quality and safety in a similar manner that previously agreed.

Since the method of manufacture has been considerably extended to obtain this High Potency Factorate, we have also examined our product according to an approved protocol under the conditions of BB-IND 1229. A detailed summary of these investigations and copies of the actual case reports are included in Volume II of this Submission.

We wish to make this application for a Product Licence and agree to permit premises of manufacture to be inspected, detailed in the attached "Omnibus" declaration under Section 19(3) of the Medicines Act.

Yours faithfully,
ARMOUR PHARMACEUTICAL COMPANY LTD.

S. G. Brooks
Regulatory Affairs Manager

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