

cc: Mr. P. B. Lloyd
Mr. E. R. James

DHSS File
R79/84

CJC/JJ

29th February, 1980

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

For the Attention of Mr. R. Smith

Dear Sirs,

PL 0231/0044
HIGH POTENCY FACTORATE

We enclose two copies of an application to vary the licensed particulars of the above product. We currently market our product Factorate (PL 0231/0038) and in November 1978 sought a licence for a high potency version of the product as above. The licence was granted on June 13, 1979. It had been our intention to launch the product in January this year, but to date the product has not been made commercially available.

During the last year, in pursuance of normal practice further development work on the product has continued and as a result, an additional stage in the manufacturing process proposed. This additional stage results in a product containing even less impurities and we believe a better product for the market. We have therefore delayed introducing the product until the more purified form was available. This is now the case and we seek to vary the licence issued last June to take into account the additional purification stage. As a result of the further purification of the product we have amended the Finished Product Specification and generated stability data on the new material,

We have already received some of this material from our US Company and samples have been passed to the NIBS & C in accordance with established procedure for the product. We would therefore very much appreciate your early attention to this application. Should you have any query relating to the information provided, the undersigned would be pleased to assist.

Yours faithfully,
ARMOUR PHARMACEUTICAL COMPANY LTD.

C.J. Collins
Regulatory Affairs Manager

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