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**Department of Health and Social Security**
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S G Brooks Esq BSc
Head of Regulatory Affairs
Armour Pharmaceuticals Limited
Hampden Park
Eastbourne
Sussex BN22 9AG

Your reference

Our reference
PL 0031/0038

Date
27 January 1976

Dear Sir

Before determining your application in respect of Factorate (Factor VIII) the licensing authority requires the following information:

a. Further details on (i) the method of assay, the standard used and the method by which it was calibrated, and (ii) batch reproducibility.

b. Confirmation that the following conditions will be observed.

i. Information will be provided by the licence holder on the number of donations from which plasma is pooled for the manufacture of each batch of the product, and the reasons for and the rate of rejection of donors or donations centre by centre.

ii. The potency of the product will be expressed in international units.

iii. The product will be stored at a temperature of 6° Centigrade or below.

iv. Product labelling will be in accordance with the British Pharmacopoeia for dried human Antihaemophilic Fraction.

v. Each batch of the product will be subject to the batch release procedure. This requires your agreement to inclusion of the following provisions in the licence:

" i. The licence holder shall on request furnish to the licensing authority from every batch of the product or from such batch or batches as the licensing authority may from time to time specify, a sample of such amount as the licensing authority may consider adequate for any examination required to be made and the licence holder shall, if required by the licensing authority, furnish full protocols of the tests which have been applied

ii. If the licensing authority so direct the licence holder shall not sell or supply any batch in respect of which a sample is or protocols are furnished under paragraph i. until a certificate authorising the sale or supply of the batch has been issued to him by the licensing authority.

iii. The licence holder shall, on being informed by the licensing authority that any part of any batch of the product has been found not to conform as regards strength, quality and purity with the specification of the product and on being directed so to do, withdraw the remainder of that batch from sale or supply and, so far as may be practicable, recall all issues already made from that batch".

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c. Confirmation that plasma will be obtained only from donor centres in the USA or in other countries specified in respect of which the licensing authority is satisfied as to the donation arrangements, being premises in respect of which you provide an undertaking that they may be inspected by or on behalf of the United Kingdom licensing authority.

This information is requested in accordance with the provisions of section 44(1) of the Medicines Act 1968. Processing of your application can then continue.

Yours faithfully

GRO-C

G H T DEVENEY
A person authorised to sign on behalf of the Secretary of State for Social Services