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Department of Health and Social Security
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N Berry Esq
Managing Director
Serological Products Limited
Arctic House, Rye Lane
Dunton Green, Nr Sevenoaks
KENT TN14 5HB

Your reference
NB/ML
Our reference
PL/0215/0006-0008
Date
14 August 1973

Dear Sir

MEDICINES ACT 1968 : LICENSING

I refer to your application dated 20 December 1972 as amended by your letters of 19 February 1973, 30 March 1973, and 11 July 1973. Authority has now been given, subject to payment of fees and the receipt of a Section 19(3) undertaking, for the grant of a product licence for:

Product	Licence Number
Prothromplex TM Partial Prothrombin Complex Factors II, IX & X (200 Units)	0215/0006
" " " (500 Units)	0215/0007
" " " (1000 Units)	0215/0008

The grant of the licence will be subject to the following provisions agreed on 11 July 1973:

(i) the final product is tested for hepatitis associated antigen

(ii) any stabilizer contained in the product should be identified on the label

(iii) the TSA batch release procedure will apply

Under the provisions of the Medicines (Fees) Regulations 1971 (SI 1971 No 1449) payment of the initial fee of £10 became due upon receipt of your application. Please send a remittance of this amount to the Department's Cashier using the special form and addressed envelope enclosed with this letter.

ENCS

The licensing authority requires the production of the undertakings and declaration referred to in Section 19(3) of the Medicines Act 1968. I should be pleased if you would arrange for these to be given by the manufacturer of the medicinal product

Osterreichisches Institut Fur Haemoderivate Ges MBH
Industriestrasse 72, 1220 Vienna, Austria.

A form of undertaking which should be used for this purpose is enclosed.

The product licence will include a provision that the number of the licence shall appear on all containers or packages in which the product is packed, on any package inserts or accompanying literature and on any data sheets issued in connection with the product.

The formal documents relating to the issue of the licence are being prepared and will be sent to you in due course.

Please let me know the date on which the product is introduced on to the market.

Yours faithfully

GRO-C