



Department of Health and Social Security

Medicines Division Finsbury Square House
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Mrs J Brazier
Scientific Information Officer
Travel Laboratories Limited
Gaxton Way
THIRFORD
Norfolk IP24 5SR

Your reference **JB/TB**
Our reference **PL/0116/0049**
Date **15 October 1976**

Dear ~~xxxxx~~ Madam,

MEDICINES ACT 1968: PART II LICENSING

I refer to your application dated **21 May 1975**. Authority has now been given for the grant of a product licence(s) for:

<u>Product</u>	<u>Licence number</u>
Proplex Factor IX Complex (Human)	PL/0116/0049

This means that you may now proceed as in your application, as amended by your letters of **22 June, 28 July and 17 September 1976**.

The licence is subject to all the Standard Provisions set out in Part I of Schedule 1 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (SI 1971 Number 972), as amended by SI 1972 Number 1226 and SI 1974 Number 1523.

The product licence(s) includes a provision that the number of the licence shall appear on all containers or packages in which the product(s) is/are packed and on any package inserts or accompanying literature and on any data sheets issued in connection with the product.

Your attention is also drawn to the final paragraph of the letter of about the reporting of suspected adverse reactions. This stated that a separate notification would be given in respect of each medicinal product which is regarded as "recently introduced" for these purposes and to which a Special Direction is to apply. Enclosed is a Special Direction by the licensing authority which applies to the above product.

Attention is also drawn to paragraph 23 of the Medicines Act Information Letter 'MAIL 10' dated November 1975, and you are asked to arrange that the entry in NIMS relating to this product and the data sheet are specially marked, as explained in that paragraph, to show that it is recently introduced.