

Department of Health and Social Security Medicines Division Finsbury Square House 33-37a Finsbury Square London EC2A 1PP

Telex GRO-C

Telephone GRO-C

Dr. W. d'A. Maycock	Your reference . Wd'AM/AH
Dr. W. d'A. Maycock Blood Products Laboratories Had Lister T. Hitchen of Production	Our reference PL 0134 0007-9
Flatree	Doto 3 February 1977
Borehamwood, Herts WD6 3AX	January 1976

Dear Sir(s)

MEDICINES ACT 1968 : PART II LICENSING

I refer to your application dated 29 March 1976 , Authority has now been given for the grant of a product licence(s) for:

Product

Licence number

DRIED HUMAN ANTIHAEMOPHILIC FRACTION - 0134/0007 - 0134/0008

(Male et Planna Fractionation (up. Oxford) - 0134/0008

DRIED HUMAN, IX FRACTION - 0134/0009

(contains also Factors 11 and x)

This means that you may now proceed as in your application, as amended by your letters of 9 November and su January 1977.

The licence is subject to all the Standard Provisions set out in Part I of Schedule 1 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (SI 1971 NO 972), as amended by SI 1972 No 1226 and SI 1974 No 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.

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The formal documents relating to the issue of the licence(5) are being prepared and will be sent to you in due course.

Please let me know the date(s) on which the product(s) is/are introduced on to the market. In this connection, you are requested to complete item 3 of the enclosed letter and return it as soon as facilitie.

Yours faithfully

GRO-C

L.M.Q. D'CRUZ

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3. Would you please state:

- a. If you are agreeable to immediate publication of the details at (2) above; or
- b. If not the date on which we may arrange publication; and
- o. The date of marketing if that date is different from the date given in answer to (a) or (b).

Has been issued to NHS for some time.

4. On completion of (3) please return this letter in the enclosed pre-addressed franked envelope.

· Yours faithfully

GRO-C

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