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Department of Health and Social Security
Medicines Division ~~Finsbury Square House~~
~~33-37a Finsbury Square London EC2A 1PP~~
~~Telex 883669~~
~~Telephone 01-638-6020 ext~~

Market Towers
1 Nine Elms Lane
Vauxhall
London SW8 5NQ
Telephone 720 2188
Telex 883669

B A Dyos Esq
Cutter Laboratories Ltd
10 Quarry Street
Guildford
Surrey GU1 3UZ

Your reference
BAD/EJV
Our reference
PL 1605/0004
Date
10 June 1980

Dear Sirs

MEDICINES ACT 1968: PART II LICENSING

I refer to your application dated 24 January 1980 as amended by your letter(s) of 6 March 1980.

Authority has now been given for the grant of a product licence for:

PRODUCT	LICENCE NUMBER
Antihemophilic Factor (Human) Koate	1605/0004

The formal documents are enclosed. If you consider they contain information which is incorrect or is not in accordance with your application and amendment(s) please return them with brief details.

In relation to the above licence you will wish to note and consider the following:

1. The licence is subject to standard provisions which are contained in the schedule to the licence.

2. Your attention is drawn to the requirements concerning the reporting of suspected adverse reactions under Article 4 of Schedule I (Part 1) to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (SI 1971 No 972). Attached is a Standard Direction which sets out these requirements.

3. All products are subject to review by the Committee on Review of Medicines: currently anti-rheumatic, analgesic, biological and psychotropic categories are under review.

4. If any data sheets for the product(s) covered by this/~~these~~ licence(s) are to be issued, will you please arrange for copies to be sent to this office. The particulars to be included in such sheets are set out in the Medicines (Data Sheet) Regulations 1972 (SI 1972 No 2076).

5. 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 attached letter and return it in the enclosed envelope as soon as possible.

6. This product is subject to batch release procedure as stated in the appropriate letter which is also enclosed.

Yours faithfully

GRO-C

MHC