MEDICINES ACT 1968

PRODUCT LICENCE No. 1605 / 0004 has been granted under and subject to the provisions of the Medicines Act 1968 to

Cutter Laboratories Limited
10 Quarry Street
Guildford
Surrey
GU1 3UZ

in respect of the products, particularly of which are set out in Part 1 of the attached Schedule. The Licence is subject to the further provisions set out or referred to in Part 2 of the said Schedule.

This Licence, unless previously suspended, revoked or varied as to the period of its validity, shall continue in force until the end of a period of five years from the date on which it was granted.

Date granted: 10 June 1980

GRO-C: R J Anderson

A person authorised to sign on behalf of the Secretary of State for Social Services.

10 June 1980

Department of Health and Social Security
Medicines Division
Market Towers
1 Nine Elms Lane
LONDON SW8 5NQ

MEDICINES ACT 1968

Product Licence No. 1605/0004

SCHEDULE

Part 1 - PARTICULARS OF THE PRODUCTS TO WHICH THE LICENCE RELATES

1.	Name of Product:	ANTIHEMOPHILIC FACTOR (HUMAN) KOATE.
2.	Pharmaceutical form:	Sterile lyophilized powder for reconstitution with sterile water for injection.
3.	Active constituents:	Factor VIII concentrate which becomes the therapeutic agent upon reconstitution with the suitable volume of sterile water for injection.
4.	Uses:	Antihemophilic Factor (Human) is indicated in the treatment of classical hemophilia (hemophilia A) in which there is a demonstrated deficiency of Factor VIII activity.
5.	Recommended dose and dosage schedule:	As specified in the application
6.	Contra-indications, Precautions and Warnings:	As specified in the application
7.	Legal category:	PRESCRIPTION ONLY MEDICINE.
8.	Method of retail sale or supply:	Prescription only medicine.
9.	Manufacturer of dosage form:	Cutter Laboratories Inc A. Antihemophilic Factor (Human) - Berkeley, California, USA - Clayton, North California, USA B. Sterile water for injection - Chatanooga, Tennessee, USA.

MEDICINES ACT 1968

Product Licence No. 1605 / 0004

SCHEDULE

Part 2 - FURTHER PROVISIONS SUBJECT TO WHICH THE LICENCE HAS BEEN GRANTED

1. All the provisions of Part I of Schedule 1 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (SI 1971 No 972) as amended by the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1972 (SI 1972 No 1226), the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1974 (SI 1974 No 1523), The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1977 (SI 1977 No 675) and the Medicines (Standard Provisions for Licences and Certificates) Amendment (No 2) Regulations 1977 (SI 1977 No 1039) shall apply.

2. Leaflets issued with proprietary medicinal products shall comply with the requirements of the Medicines (Leaflets) Regulations 1977 (SI 1977 No 1058). Labels of medicinal products shall comply with the Medicines (Labelling) Regulations 1976 (SI 1976 No 1726) as amended by the Medicines (Labelling) Amendment Regulations 1977 (SI 1977 No 996).

3. The product(s) shall not be recommended to be used for any purposes other than those specified in Part 1 of this Schedule as Uses.

4. The specification of the constituent and of the finished product shall be in accordance with the information contained in the application for this product licence.

5. The product shall be manufactured only in accordance with the method given in the application for this product licence.