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

Telex 883669 Telegrams Healthmin London SE1
Telephone 01-638 6020 ext GRO-C

Your reference NB/JB

Our reference PL/0215/0003

Date 22 March 1973

N Berry Esq
Managing Director
Serological Products Ltd
6th Floor, Regina House
5 Queen Street, London EC4N 1SP

Dear Sir

MEDICINES ACT 1968 : PART II LICENSING

With reference to your application dated 8 December 1972 the licensing authority proposes to grant a product licence for:

Product	Licence number
Kryobulin ™ - Human Antihaemophilic Fraction BP	0215/0003

The grant of the licence will be subject to the amendments agreed to in your letter of 27 February 1973 as follows:

(i) the potency of the product is expressed in international unit,

(ii) the supply of the product is restricted to hospitals and haemophilia centres.

The licence will include a provision that the provisions as set out in regulations 4(g) (h) and (i) of the Therapeutic Substances (Manufacture and Importation) General Regulations 1963 (SI 1963/1450) shall apply.

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

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

E. J. NICHOLAS