38A

JC11

GRO-C

345

BLS/SFR

PL/0116/0011

19 February 1973

B L Steer Esq
Managing Director
Travenol Laboratories Ltd
Caxton Way
Thetford
Norfolk

Dear Sir

MEDICINES ACT 1968: PART II LICENSING

With reference to your application dated 3 November 1972, as amended by your letters dated 3 and 5 January and 5 February 1973, the licensing authority proposes to grant a product licence for:

Product	Licence number
HEMOFIL Antihaemophilic Factor (Human)	0116/0011

The Medicines (Fees) Regulations 1971 (SI 1971 No 1449) provide that one duration fee is payable by a product licence holder for all of his product licences that are to expire during the same calendar year. It follows that a further duration fee for each year of validity is payable for product licences granted in 1973 and which are due to expire in 1978. However, consideration is being given to proposals for an amendment to the regulations so as to remove the requirement to pay a second duration fee in respect of years covered by the existing licence. In the circumstances no request for payment of the further duration fee is being made at present; this is without prejudice to your liability for payment if the requirement is not removed or to your liability in respect of the additional year.

The grant of the licence will be subject to the amendments agreed to in your letter dated 5 February 1973, as follows

(i) the potency of the product will be expressed in international units

(ii) the supply of the product will be restricted to hospitals and Haemophilia Centres

(iii) the provisions set out in Regulation 4(g), (h), and (i) of the Therapeutic Substances (Manufacture and Importation) General Regulations 1963. (SI 1963 No 1450) shall apply.

1

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