

MEDICINES ACTS 1968 AND 1971

APPLICATION FOR RENEWAL OF PRODUCT LICENCE

Please read notes on page 2 before completing this form.

A. Licence Holder: TRAVENOL LABORATORIES LTD.,
Caxton Way,
Thetford, Norfolk IP24 3SE

B. Particulars of Present Licence: (i) Number: PL 0116/0049
(ii) Date Granted: 15 October 1976
(iii) Date of Expiry: 15 October 1981

C. Products Covered: PROPLEX
Factor IX Complex (Human)

D. Dates of any variations or changes in the original particulars:
Letters of 22 June 1976, 28 July 1976, 17 September 1976.
Variations of 15 November 1976, 20 April 1979, 12 February 1980.

E. Any further material change in particulars:
(i) Changes in product particulars - see page 2 of attached amendments.
(ii) Changes in Chemistry and Pharmacy - see pages 3 - 36 of attached amendments.

F. Any condition of provision other than those in existing licence:
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G. If any further documents are attached, give number of pages and a brief description: See E above.

H. I/We apply for the renewal of the product licence described above for a period of 5 years from the date of expiry given above. The licence as renewed shall be in accordance with the particulars given above and on any accompanying documents, and those given in the original application as amended by the letters referred to in D above. The licence shall further be subject to the following provisions except as specified in F above:

- (a) all the provisions of the existing licence as now in force
- (b) except where they conflict with the provisions of the existing licence, all the standard provisions applicable to product licences under regulations for the time being in force under section 47 of the Medicines Act 1968.

Date: 20 August 1981

Signature:

GRO-C

State capacity in which signed.

C.A.M. Chard, B.Sc., M.P.S.

Scientific and Regulatory Affairs Manager

Name and address for communications:

Travenol Laboratories Limited,
Caxton Way, THETFORD,
Norfolk IP24 3SE

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Pharmaceutical Data

For the purpose of renewal, assurances are required that the pharmaceutical information on file relating to each product is current and complete. For this purpose items 1-6 below must be completed and signed as an accurate record.

- (a) Where the data in the original application is out-of-date and does not accurately reflect the current situation revised data should be attached. This should be indicated by ticking the appropriate box.
- (b) In all other cases ie where the original application or a subsequent variation provided information which is still valid a reference to the specific documents should be given.

Stability Data

Where complete information was not given in the original application or subsequent up-dates, data is required to support the proposed shelf life of the product(s). If the label does not include an expiry date evidence is required that the product is stable for a minimum of three years under the recommended conditions of storage.

Please complete the following:-

- | | Attached | Supplied Previously
(give exact reference) |
|--|-------------------------------------|---|
| 1. Method of Manufacture
and In-Process Control | <input checked="" type="checkbox"/> | |
| 2. Ingredient Specifications | <input type="checkbox"/> | |
| 3. Finished Product Specification | <input checked="" type="checkbox"/> | |
| 4. Stability Data | <input type="checkbox"/> | |
| 5. What is the shelf life of
the product? | 2 years
..... | |
| 6. Is an expiry date included on the label? | | YES/ NO |

Date 20 August 1981

Signature:

GRO-C

State capacity in which signed

C.A.M. Chard, B.Sc., M.P.S.

Scientific and Regulatory Affairs Manager