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Department of Health and Social Security
Medicines Division Finsbury Square House
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Mrs J M Boult BPharm MPS
Registration Officer
Bayer UK Limited
Pharmaceutical Division
Haywards Heath
West Sussex
RH16 1TP

Your reference

Our reference

Date

2 February 1976

Dear Mrs Boult

ANTI-HAEMOPHILIC FACTOR (HUMAN) KOATE - PL/0010/0061

You will be pleased to hear that the above licence application has now been considered and that the grant of a product licence has been advised for the purposes indicated in the application on condition that:

1. Satisfactory information is provided on

   (a) the number of donations in each pool;

   (b) the method of assay, the standard used and its calibration;

   (c) batch to batch reproducibility.

2. The product labelling complies with the BP, including the use of international units of potency, and showing the upper limit of the storage temperature as 6°C.

3. The expiry date is given together with temperature at which the investigation was performed.

4. On-going information is provided on the reasons for, and the rate of, rejection of donors or donations, centre by centre.

5. The applicant shall agree to the imposition of the batch release procedure, to be applied at the licensing authority's discretion.

The above information is requested under Section 44 of the Act. In accordance with that Section, the licensing authority will not continue assessment of this application until such time as you have provided this information or have given a satisfactory reason why it cannot be provided.

Yours sincerely

GRO-C

R D Andrews
Senior Medical Officer