



Department of Health and Social Security

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Mrs J M Boulton BPharm MPS
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Pharmaceutical Division
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Your reference

Our reference

Date

11 March 1976

Dear Mrs Boulton

Thank you for your letter of 27 February 1976 relating to information requested in my letter of 2 February.

Much of the information requested has been supplied except for the following which is requested under Section 44 of the Medicines Act.

1. Method of assay, house standard and analysis of results

Information on the house standard - if this is a production lot then a protocol for it would be acceptable.

Information on its calibration against the International Standard for Factor VIII, by a biometrically balanced assay design; this should include raw data, its statistical analysis by conventional methods for validity of combining results; so that the potency of the standard is stated in i.u. with (95%) fiducial or confidence limits.

Information on the stability of this house standard should be provided - in the form of accelerated degradation tests and the temperature of storage.

2. Batch to batch reproducibility

The batch numbers given as evidence for consecutive batch to batch reproducibility are M 046566, - 69 and 70; could you please forward batches - 67 and - 68.

3. Labelling

A statement of "not more than g or ml/litre" would be acceptable for eg fibrinogen, citrate, sodium chloride; the term "minimal concentration" has little quantitative precision.

Although the filter needle is provided it would still be desirable to include the BP instruction not to use the product if a gel forms: someone might replace the (filter) needle thinking it was blocked.

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I enclose two reprints on the international standard and its use.

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