No.

CT 3070/0006

Cov.

Speywood Laboratories Ltd

Product

Mono-VIII C

Therapeutic Class

Blood Product

Active Constituent

Human Factor VIII

24.3.83

Main Committee

Advice

On the evidence before them the Committee had reason to think that on grounds relating to safety and quality they would be unable to advise the grant of a clinical trial certificate for this preparation and directed the Secretary to notify the applicant in accordance with Section 21(1) of the Act.

The Committee provisionally concluded that:

Bulk Cryoprecipitate

1. the bulk cryoprecipitate should be prepared by Alpha Therapeutics only from Source Plasma (Human) derived from their own licensed plasmapheresis centres,

2. evidence should be provided to show that the cryoprecipitate is at least equivalent in quality to that used for the manufacture of Alpha Therapeutic's US licensed Factor VIII,

3. inadequate information was presented on the control of the cryoprecipitate during transport to the UK,

4. inadequate information had been provided on the control of the quality of the cryoprecipitate on arrival in this country and throughout its transit in the UK,

5. donor lists should be available to Speywood Laboratories Ltd as manufacturer of the finished dosage form,

6. inadequate details of the manufacturing process of the bulk cryoprecipitate were supplied,

Mono VIII : C

7. full details should be supplied on the manufacturing and control methods of the product. This should include definitive information on in-process sterilisation methods and microbiological control,

8. reverse osmosis water should not be used in the preparation of this product,

9. bubble-point testing should be carried out on the sterilising filter before and after filtration,

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10. the FPS should include tests and limits for Loss on Drying, Isoagglutinins and Pre Kallikrein Activator,

11. full information should be supplied on the manufacture and quality control of the 5 ml diluent supplied with the injection,

12. in the event of a Clinical Trial Certificate being issued the study should be limited to 10 patients and to no more than one bleeding episode in each patient.

Remarks

1. By Product Licence Stage:

1.1 evidence should be provided to show that the manufacturing process yields a consistent product,

1.2 evidence should be provided concerning the long term toxicity of the product and its possible contaminants,

1.3 evidence of clinical pharmacology of the product would be required.

2. In the event of a clinical trial certificate being issued for this product, the batch release procedure should apply, to include the provision of protocols and samples of bulks, as required.