No.

PL 4447/0004

Cov.

Alpha Therapeutic (UK) Ltd

Product

Antihaemophilic Factor (Human) Wet-Paste (Bulk Cryoprecipitate)

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 product licence 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:

1. the bulk cryoprecipitate should be prepared by Alpha Therapeutic 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 material during transport to the UK,

4. an undertaking should be given that donor lists should be available to the manufacturer of the finished dosage form,

5. in the event of a licence being granted for this product, the batch release procedure should apply, to include the provision of protocols and samples of bulks, as required,

6. there were inadequate details on the manufacturing process.

Remarks

1. The Licensing Authority is asked to consider the legal implications of licensing this bulk blood product as an ingredient rather than as a finished product, especially in view of the great difficulties foreseen for the manufacturer of the finished dosage form in exercising full control going back to the source material.

2. The Committee advised that special attention be given to the inspection of the Company's premises in the USA.

3. The Committee noted that no evidence of efficacy was provided as the product was intended only as an ingredient.

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