OR

COMMERCIAL IN CONFIDENCE	NUMBER: CT 3070/0006
APPLICATION FOR A CLINICAL TRIAL CERTIFICATE	PRODUCT NAME: MONO-VIII: C
PROPOSED CERTIFICATE/LICENCE HOLDER: Speywood Laboratories Ltd, Chancel House, East Street, Bingham, Nottingham NG13 8DR	THERAPEUTIC CLASSIFICATION: BLOOD PRODUCT
	RECEIVED: 20.10.82
	MEETING: PSM 4.11.82 BIOL MARCH 1983
MANUFACTURER OF DOSAGE FORM: As above	COMMITTEE ON SAFETY OF MEDICINES
	SUB-COMMITTEE ON BIOLOGICALS
LEGAL STATUS: CT ONLY	CONSIDERATION BY OTHER COMMITTEES:
SALE/SUPPLY:	ASSESSED BY: Dr L K Fowler, Mr J P Betts

1. PRODUCT SUMMARY

1.1. DRUG SUBSTANCE: Human Factor VIII: C, plasma protein fraction (antihaemophilic factor).

1.2. Manufacture of Drug Substance:

Bulk Cryoprecipitate manufactured by: Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles
California 90032

1.3. Product Description: A sterile white lyophilised powder presented in a 20 ml glass vial, for reconstitution with 5 ml Water for Injections BP.

1.4. Complete Formula

Active Constituents	per vial
Human Factor VIII	250 I.U.
Other Constituents	
Human Albumin	NMT 50 mg
Sodium Chloride	NMT 43.5 mg
Trisodium citrate	NMT 29.4 mg
Tris (hydroxymethyl) aminomethane	NMT 12.1 mg
Polyethylene Glycol 3400	NMT 50 mg

1.5. Proposed Uses

1.5.1. Indications: Mono-VIII-C is to be studied for efficacy and clinical tolerance in the treatment of haemarthrose involving the knees, elbows and ankles of severe haemophiliacs.

1.5.2. Dosage

Administered doses will be related closely to body weight and should not deviate by more than 1 u/Kg from the desired dose. The dose will be claculated to produce different percentage rises of FVIII dependent upon the site and severity of bleeds, as follows: A 10% rise for uncomplicated ankle bleeds; a 20% rise for complicated ankle bleeds and uncomplicated knee and elbow bleeds, and a 40% rise for all bleeds showing at least two of the three risk-factors - pain, tenderness and a loss of more than 50% of baseline movement on presentation.

The amount of factor VIII required to produce the desired response will be calculated assuming a 1.5% rise per unit/Kg in those patients with a surface area of less than 1.7 and assuming a 2.7% rise per unit/Kg for those with higher surface areas. (A. Aronstam et al, J.Clin. Pathol., 35, 289-91 (1982)).