

Armour Pharmaceutical Company Limited

St. Leonards House, St. Leonards Road, Eastbourne, Sussex BN21 3YG Telephone: Eastbourne (0323) 21422 Telex: 87141

AI000176/1

WJT/JJ

13th March, 1984

Department of Health and Social Security, Medicines Division, The Registration Section Room 1019-20, Market Towers, 1 Nine Elms Lane, Vauxhall, LONDON, SW8 5NQ

For the Attention of Mr. R. M. Saunders

Dear Sirs,

CTX 0231/0070A

HEAT-TREATED FACTORATE

We wish to add the following additional investigators to our Clinical Trial Exemption 0231/0070A for Heat-treated Factorate:

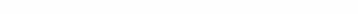
Dr. Anna Pettigrew, Royal Hospital for Sick Children, Yorkhill, Glasgow, G3 8SJ

Or. I. M. Hann, Royal Hospital for Sick Children, Yorkhill, Glasgow, G3 8SJ

Professor R. M. Hardisty, The Hospital for Sick Children, Great Ormond Street, London, WC1N 3JH

In additional please find attached a Form MLA 165 in respect of our wish to include in the protocol an optional sampling scheme for use at the discretion of the physician in situations, eg use in young children, where the existing scheme is considered to be too extensive.

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Registered Office: St. Leonards House, St. Leonards Road, Eastbourne, Sussex BN21 3YG Registered in England No. 1622483

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Department of Health and Social Security

We trust this is in order and would be grateful for your early confirmation of this.

Many thanks.

Yours faithfully, ARMOUR PHARMACEUTICAL COMPANY LIMITED

_____/ GRO-C

V.J. TARBIT Regulatory Affairs Department

ARMOUR001308

STIFICATION OF CHANGE TO A CLINICAL TRIAL EX	ZIPTION FORM: MLA 16	20
<pre>mpany Name: Armour Pharmaceutical Co. Ltd. roduct Name/Code: Heat-treated Factorate .gned: GRO-C .TURE OF CHANGE(S):(Please tick)</pre>	CTX	1984 • 0176/3
Name of Product(or Code)	Trial Duration	-
Name and/or Address of Manufacturer	Indication	
Dosage	Selection/Withdrawal Crite	ria
Active Ingredients	Investigator	
Route of Synthesis	Nature and/or Purpose of T	rial
Janufacture of Finished Product	Number of Patients	
Specification of Finished Product	Monitoring Procedures	
] Route of Administration	X Others (Please Specify)	
MAILS OF CHANGE(S): (Please be brief)	Sampling frequency	

t is proposed that in patients where sampling frequency reduction is considered by he physician to be necessary, an alternative system of sampling at pre treatment and , 12, 16, 26, 36 and 52 weeks post transfusion be used in place of the normal chedule presented on page 5 of the protocol for this study.

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ompany Notified:

Simed:....

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