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

Dr. 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.

...../2

AI000176/2

13th March, 1984

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

M. J. TARBIT
Regulatory Affairs Department

NOTIFICATION OF CHANGE TO A CLINICAL TRIAL EXEMPTION FORM:MLA 165

Company Name: Armour Pharmaceutical Co. Ltd. CTX 0231 / 0070 ...

Product Name/Code: Heat-treated Factorate Notification dated: 13th March, 1984

Signed: GRO-C .....

AI000176/3

NATURE OF CHANGE(S):(Please tick)

- [ ] Name of Product(or Code)
- [ ] Name and/or Address of Manufacturer
- [ ] Dosage
- [ ] Active Ingredients
- [ ] Route of Synthesis
- [ ] Manufacture of Finished Product
- [ ] Specification of Finished Product
- [ ] Route of Administration
- [ ] Trial Duration
- [ ] Indication
- [ ] Selection/Withdrawal Criteria
- [ ] Investigator
- [ ] Nature and/or Purpose of Trial
- [ ] Number of Patients
- [ ] Monitoring Procedures
- [X] Others (Please Specify)

Sampling frequency

DETAILS OF CHANGE(S):(Please be brief)

It is proposed that in patients where sampling frequency reduction is considered by the 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 schedule presented on page 5 of the protocol for this study.

FOR OFFICIAL USE ONLY

Date Received:.....

Referred to:

Med.Contact:..... APPROVED/REFUSED Signed:..... Date:.....

Pharm.Contact:..... APPROVED/REFUSED Signed:..... Date:.....

Remarks and Reasons for Refusal (as applicable)

Company Notified:..... Signed:.....

ARMOUR001309

ARMO0000137_0003