## REVION HEALTH CARE (UK) LIMITED

St. Leonards House, St. Leonards Road, Eastbourne, Sussex BN21 3YG Telephone: Eastbourne (0323) 21422/641144 Telex: GRO-C

RBC/EB/6939

January 18, 1985

Adverse Reactic & Monitoring Unit, Committee on Salaty of Medicines, Market Towers, 1, Nine Elms Lane, LONDON, SW8 5NQ.

Dear Sirs,

I enclose a Report on Suspected Toxicity or Side Effects relating to a report of Hepatitis B occurring in a patient being treated with Factorate Batches X47408 and Y67101.

Both of these batches have been widely distributed throughout the U.K. and probably are all administered to patients. We have not, to date, received any further reports of hepatitis or abnormal liver function tests related to their use.

We will, of course, be alert to any adverse reports involving these two batches of Factorate and will advise you accordingly should they occur.

Yours sincerely,

**GRO-C** 

R. B. Christie, DIRECTOR OF CLINICAL SCIENCES

Enc.



**Armour Pharmaceutical** Company Limited

Registered Office: St. Leonards House St. Leonards Road. Eastbourne. Sussex 8N2: 3YG

cc: Mr. C.J. Collins

Mr. C.R. Bishop

Mr. P.B. Lloyd

Mr. C. Blatchford

ARMOUR001387

CSM/AR/IND B/M272/086

## REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS For the information of THE COMMITTEE ON SAFETY OF MEDICINES

## NOTES FOR GUIDANCE

- 1. For all drugs, please record serious or unusual reactions. For new drugs record all reactions.
- 2. Record, on the top line, the drug suspected of causing harmful effects to the patient at normal dosage.
- Record all other drugs, including self-medication, taken in the previous 3 months. With congenital abnormalities, record all drugs taken during pregnancy.
- . Please do not be deterred from reporting because some details are not known.

Name of Patient: Required in confidence to Illow linkage with other reports for same patient)  ex  Age or Date of Birth  Weight if known  MALE  19 YEARS  NOT KNOWN			From (Name and address): Company doctor or other representative of product licence holder— R.B. CHRISTIE REVLON HEALTH CARE (U.K.) LTD. ST. LECNARD'S HOUSE, ST. LECNARD'S ROAD EASTBOURNE / FAST SUSSEX Signed: GRO-C Date: 18 1 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		
<del>                                     </del>		DATES			
UTE D	OSE	From	То	INDICATIONS	
7. 333	0 iu.	14/9/84	21/9/84	SEVERE HAEMOPHILIA A	
7965	0. iu.	14/9/84	PRESENT	HAEMARTHROSIS,	
			•••••		
				/*** *********************************	
~		•••••			
REACTIONS (List separately)			Ended.	OUTCOME (e.g. fatal: recovered)	
JAUNDICE, RAISED LFT's,			, 10	PATIENT'S CONDITION	
"BSAG POSITIVE TEST ON 27/12/84				NOW DESCRIBED AS "GOOD."	
PREVIOUSLY NEGATIVE) IDICATIVE OF			entire april 1	4 4 4	
		•••••	•••••		
	TE D  7. 333	TE NOWN  TO KNOWN  TO KNOWN  TO DOSE  To 3330 iu.  9650 iu.	Compariment	Company doctor or licence holder— R.I. REVLON HEALTH (ST. LECNARD'S I EASTBOURME / E. Signed: GRO-  Signed: GRO-  Name of patient's own DR. G. SAVIDGE, G. ST. THOMAS' HOSP:  THOMAS' HOSP:  DATES  From To  7. 3330 iu. 14/9/84 21/9/84  7. 9650 iii. 14/9/84 PRESENT.  Started Ended.  12/12/84	

Additional Notes BOTH BATCHES OF FACTORATE HAVE BEEN WIDELY DISTRIBUTED THROUGHOUT THE U.K. TO 10 DIFFERENT CENTRES. FROM DATES OF ISSUE MOST SHOULD HAVE BEEN ADMINISTERED BY NOW... NO OTHER REPORTS OF HEPATITIS OR ABNORMAL LIVER FUNCTION TESTS HAVE BEEN RECEIVED.

THE PATIENT HAD NO PREVIOUS HISTORY OF HEPATITIS NOR ANY KNOWN CONTACT.