REVLON HEALTH CARE (UK) LIMITED

St. Leonards House, St. Leonards Road, Eastbourne, Sussex BN21 3YG
Telephone: Eastbourne (0323) 21422/641144 Telex: 87141/877052

RBC/EB/6043

7 September, 1984

The Medical Assessor,
Committee on Safety of Medicines,
Market Towers,
1, Nine Elms Lane,
Vauxhall,
LONDON, SW8 5NL.

Dear Sir,

I enclose a Report on Suspected Toxicity or Side Effects covering right hypochondrial tenderness, raised LFTs and positive HBsAg and HBeAg values on a haemophiliac patient at the Hammersmith Hospital, London, following treatment with Factorate and Blood Products Laboratory Factor VIII.

All of these batches of Factorate involved have been widely distributed and the multiplicity of materials administered between the last negative HBsAg result and the positive test makes a definitive assessment of the situation difficult. We have had a single report of clinical Hepatitis B in another patient, again with multiple treatment, part of which involved two of the batches given to H.H. No other adverse reactions covering these two batches have been reported to us.

Yours faithfully,

GRO-C

R. B. Christie,
DIRECTOR OF CLINICAL SCIENCES

Enc.

cc: Dr. H. L. Shaw
Mr. C. J. Collins
Mr. C. R. Bishop
Mr. C. Blatchford
Miss J. Medlock

ARMOUR001350

ARMO0000152_0001

IN CONFIDENCE

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.
3. Record all other drugs, including self-medication, taken in the previous 3 months. With congenital abnormalities, record all drugs taken during pregnancy.
4. Please do not be deterred from reporting because some details are not known.

Name of Patient: Required in confidence to allow linkage with other reports for same patient) [redacted] Hospital No. [redacted]

From (Name and address): Company doctor or other representative of product licence holder— R. B. CHRISTIE, DIRECTOR, CLINICAL SCIENCES, REVLON HEALTH CARE (U.K.) LTD., ST. LEONARD'S HOUSE, ST. LEONARD'S ROAD, EASTBOURNE, EAST SUSSEX.
Signed: Date:

Sex	Age or Date of Birth	Weight if known	Name of patient's own doctor (and address if known):
MALE	D.O.B. [redacted]	60 Kg approx.	DR. S. BALL, HAEMOPHILIA CENTRE, HAMMERSMITH HOSPITAL, DUCANE ROAD, LONDON, W12 0HS.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES From	DATES To	INDICATIONS
FACTORATE X43803	I.V.	26 bottles	Feb.	1984	MODERATE HAEMOPHILIA
FACTORATE X42791	I.V.	10 "	Feb.	1984	WITH FACTOR VIII
FACTORATE X52509	I.V.	24 "	April	1984	INHIBITORS
FACTORATE X21902	I.V.	4 "	April	1984	
FACTORATE X60511	I.V.	4 "	June	1984	
BPL FACTOR VIII	I.V.	6 "	30/1/84		
BPL FACTOR VIII	I.V.	4 "	5/2/84		
BPL FACTOR VIII	I.V.	4 "	5/3/84		
(*For Vaccines give Batch No.)					

REACTIONS (List separately)	Started	Ended	OUTCOME (e.g. fatal: recovered)
Very high titre positive HBsAg, HBeAg			
Raised LFT's, Right hypochondrial discomfort and tenderness. Not jaundiced. Suspected Hepatitis B.	Detected July 1984 (tests negative January 1984)		Recovered

Additional Notes

These batches of Factorate have been widely distributed in the U.K. and overseas. A single repeat involving X52509 and X21902 assaying a mixture of other batches and FEIBA has been received. See my yellow form dated 20/8/1984. No other adverse reactions to any of these batches has been received.

ARMOUR001351

ARMO0000152_0002