MILES

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BAD/ey

Mr. John Ayling,
Dept. of Health and Social Security,
Market Towers,
1 Nine Elms Lane,
LONDON, SW8 5NQ.

11 February, 1986

Dear Mr. Ayling,

KOATE HT - Lot 50P025

Further to our telephone conversation of 10 February, 1986 regarding the above product, the following information is provided per your request.

1. Release certificate for Lot 50P025 dated 18.6.85, copy attached.

2. 4500 vials imported for sale, June 1985.

3. Product supplied to the following Haemophilia Centres:-

Oxford	1512	vials
Manchester	1415	"
Newcastle	680	"
Leicester	400	"
Bristol	200	"
Bangor	192	"
	4399	"
Remaining in inventory	101	"
	4500	"

Cont/...

4. On 22 July 1985, a report from our field representative was communicated to our Medical Director, Dr. B. Elliott at Miles Laboratories, that reactions to Lot 50P025 had occurred at the Manchester Children's Hospital, Pendlebury. The reactions reported by Dr. D.I.K. Evans were discussed by Dr. Elliott and Dr. Evans on 23 July, 1985 and the information obtained was communicated by telephone to appropriate personnel at Cutter Laboratories in Emeryville.

5. On 26 July, 1985, a telex was sent to Cutter, Emeryville confirming the details received from Dr. Evans together with comments obtained from Dr. Matthews of the Oxford centre. (Copy attached).

6. It was agreed with Dr. Evans that an alternative batch of product be supplied for those patients that had reacted to Lot 50P025 and a supply was forwarded to Manchester. It was also agreed that Dr. Evans and Dr. Elliott would follow up on the alternative batch of product.

7. The remaining centres that had received Lot 50P025 had been contacted to ascertain if any reactions similar to those observed in Manchester had been reported. No such reports had been received, and the centres in question confirmed that they were happy to continue to use Lot 50P025.

8. On 1 August, 1985, a telex was received from John Cherry, Director of Quality Assurance, Cutter Emeryville, (copy attached), advising of a voluntary recall in the U.S. involving 3 lots of Koate HT. None of the lots recalled were U.K. lots.

9. In view of the fact that similar mild reactions to those reported by the Manchester centre had been experienced with the 3 lots recalled in the U.S., Dr. Elliott decided to quarantine the remainder of Lot 50P025 as a precaution pending further investigation.

10. A telex dated 10 February, 1986 (copy attached) from Cutter Emeryville, confirms the 3 lots that were recalled in the U.S. and explains the action taken.

It would appear from the information provided above that the "Pink Sheet" report has incorrectly implicated Lot 50P025. I will be pleased to provide any further information you may require.

Yours sincerely,

GRO-C

Brian A. Dyos
Business Manager

cc: Jack Wood
Dr. B.A. Elliott