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Cutter Laboratories

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Our Ref MWT/svs

23rd December 1986.

Department of Health & Social Security,
Market Towers,
1, Nine Elms Lane,
Vauxhall,
London,
SW8 5NQ.

Dear Sirs,

KOATE HT PL 0055/0107 : BATCH RECALL

We wish to inform you that a batch of Koate HT (BN 50P069) has been recalled by Cutter Laboratories U.S.A. following investigations into a report of the possible association of this batch with the development of Hepatitis B in recipients in Eire.

All U.K. haemophilia centres supplied with this batch were contacted and advised of this report. In all instances the product had already been used with no adverse effects. There were no stocks remaining in the U.K. and thus a recall in this country was not necessary.

The report was investigated by Cutter as follows:-

1. The routine release test for Hepatitis B Surface Antigen (Radioimmunoassay) was repeated on retained samples of batch 50P069 and all results were negative. The tests were carried out in Cutter's Q.A. laboratories in both Berkeley and Clayton.
2. In compliance with regulations, all units of plasma used in production of Koate HT are routinely tested for Hepatitis B Surface Antigen and any unit found to be positive is destroyed.

In order to further assure that none of Cutter's plasma-derived products are contaminated with HBsAg, the company has now initiated testing of plasma pools.

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During the validation of this procedure, retained samples from 39 pools were tested for HBsAg and one was found to be positive.

The positive pool was used in the production of Koate HT batch 50P069.

We currently have no explanation for this since all plasma units were subjected to the normal rigid controls but we wish to inform you that the testing of plasma pools was implemented on December 15th, 1986, and is now included in the release specification for all Cutter's coagulation products.

We also confirm that there are no stocks remaining in the U.K. and no reports of hepatitis have been received from the centres supplied with this batch.

Yours faithfully,

GRO-C

Marie W. Tatt (Mrs.),
Regulatory Affairs Manager.