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Our Ref MWT/svs

23rd December 1986.

Dr. A. Scott,
Medical Director,
National Drugs Advisory Board,
63-64, Adelaide Road,
Dublin 2.

Dear Dr. Scott,

KOATE HT : PA 79/15/4-6 - HEPATITIS REPORT

Further to my letter of 16th July, 1986, I am writing to inform you of the results of the investigations carried out on the batch of Koate HT which was reported to have transmitted Hepatitis B in three of Professor Temperley's patients.

The routine release test for Hepatitis B Surface Antigen (Radioimmunoassay) was repeated on retained samples of the suspect batch 50P069. The tests were carried out by our Q.A. laboratories in both Berkeley and Clayton and all results were negative.

In compliance with regulatory requirements, all units of plasma used in production 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.

During the validation of this procedure, retained samples from 39 pools were tested 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 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 coagulation products.

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We will be writing to Professor Temperley to inform him of the results of these investigations.

As previously reported, all remaining stocks were withdrawn from circulation and quarantined pending the results of these investigations and will now be destroyed.

Yours sincerely,

GRO-C

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