

# Bayer



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Your ref

Our ref

CDS/ER/119

Date

27 July 1989

Dear Eli,

KOATE HT : LOT NO. 55U011A

Further to our telephone conversation yesterday, I am writing to inform you that this morning, Dr. Thomas (NIBSC) contacted me to say that the above lot of Koate HT will not be released by NIBSC. The reason for this is as follows:

Upon initial testing of the samples, a weakly positive (equivocal) result with regard to the presence of HBsAg was obtained for the product. The plasma pool was negative. Re-testing of both plasma pool and product gave similar results. Since the weakly positive result could be neutralised with specific antibodies to HBsAg, they feel that, on balance, the lot should not be released. They have not observed such results with our products before. In due course, we will be notified in writing by the Department of Health.

I anticipate that you, or your colleagues, may wish to contact NIBSC to obtain further information on this matter. I would be grateful if such communication could be co-ordinated through our registration department or, at least, that we are kept fully informed of the outcome of any such discussions.

Unfortunately, I am on holiday next week (31 July - 4 August) but please do not hesitate to contact Joyce Boulton (Registration Manager - direct dial **GRO-C**) if necessary.

I look forward to hearing from you on this matter in due course.

Regards.

Yours sincerely,

GRO-C

Craig D. Simpson  
SENIOR REGISTRATION OFFICER  
cc: Debby McCormick  
Marsha Quinton  
Donald Lee

For: M. Schneider, Chairman J.V. Webb, Managing, R. Korn, Lord Walton

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