

2 AUG

INTRODUCTION

This batch became the subject for withdrawal procedure in March 1988 following a report from Plymouth of Hepatitis B in three patients. It was agreed that customers who had received this batch would be notified. Unused quantities of Koate 50S021 were to be quarantined and returned to Cutter for credit.

The CSM were notified on the Yellow Card System and Cutter instituted their recall system using direct phone contact. It was not deemed necessary to make any announcements or notify customers in writing.

Shortly after this event Cutter distribution was passed to Bayer UK Limited and subsequently contact with the DHSS was undertaken by Joyce Boulton.

METHOD OF DISTRIBUTION

Batch 50S021 was imported from Cutter USA on export invoice number 23-249.

The stated quantity was 8092 vials. This quantity was stored at Stoke Court and a simple T card was issued for stock control. The goods were booked in on 1st June 1987. On receipt of an order an advice note was raised and this quantity and reference was entered on the stock control card. An invoice was raised carrying all the relevant information.

METHOD OF RECALL

The stock card reference allows identification of all customers via the advice note and invoice. In the case of BN 50S021 this was done and all customers contacted. Most Returns were sent to Miles Bridgend and a small quantity to Bayer Newbury.

VALIDATION

	VIALS
Batch 50S021 invoiced and recorded as	
Invoiced sales, including free goods	8092
Book balance	<u>7812</u>
Physical check balance	280
Goods not accounted for	<u>46</u>
	234
Returned Goods	
Bridgend	
Newbury	987
	<u>91</u>
Held by Accuscience	1078
	<u>22</u>
	1100
Estimated quantity of batch used	6946

Attempts to check the 234 vials not accounted for have been unsuccessful. In view of the fact that bonus goods were taken from stock it must be assumed that the missing 234 vials were either used as bonus or samples and not recorded.

ACTION FOR FUTURE

Cutter products will in future be distributed from the Central Warehouse Bromsgrove. The system in use will make stock control "foolproof" and the system does not allow for goods to be removed without paperwork.

A quantity of emergency stock stored in Newbury must only be used with proper recording.

If a recall becomes necessary in the future users must be notified in writing.

DAL/2nd August 1988

Distribution: B Aundrup, ~~P. Bond~~, R Cuff, L Frith.