

Miles



Miles Pharmaceuticals
Division of Miles Laboratories, Inc.

VIA: International Air Mail

May 14, 1987

400 Morgan Lane
West Haven, Connecticut 06516
(203) 934-9221

Dr. V. E. Mitchell
Consultant Hematologist
Leicester Royal Infirmary
Leicester, England LE15WN

Dear Dr. Mitchell:

This letter is in response to a report received via our U. K. office regarding development of hepatitis B in a patient under your care. We understand that this individual had undergone coronary bypass surgery, and that prior to surgery, had been determined HBAG and HBAB negative; however, four months later tested HBAG positive. It is also our understanding that he had been given two injections of hepatitis B vaccine prior to surgery, and that during and/or following the operative procedure, received two units of whole blood, 6 units of platelets, and infusions of Koate^{HT}, Antihemophilic Factor Human, Heat-treated. This was from Lot 50R004.

We have had no other reports of any type of adverse reaction, including hepatitis, with respect to Lot 50R004. A review of all manufacturing records and QA evaluations are normal for this Lot. Each unit of plasma which went into this production batch was hepatitis B antigen negative, and RIA testing of the Lot itself was HBAG negative.

In view of the foregoing laboratory studies, with the lack of other hepatitis reports regarding this Lot, and considering the patient's having received blood and platelets, we do not believe Koate^{HT} to be the probable source for his hepatitis B.

Cordially yours,

GRO-C

G. M. Akin, M. D., FRSH
Associate Director
Professional Services

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