Interoffice
Communication

MILES

Berkeley, CA

Date December 19, 1986

Subject Recall Koāte® HT (AHF), Lot 50P069

From Jean Huxsoll

To Ms. Marie Tatt

The subject of this communication is to direct a corrective action by recall of Koāte® HT (AHF), Lot 50P069, from your markets.

Occasionally we receive reports from health practitioners that one of our human plasma derived products could possibly have been associated with a patient contracting hepatitis. Such reports are usually associated with concomitant patient care which, among other therapies, will have included Cutter products. When such reports are received, samples are requested so that analytical tests can confirm whether, in fact, the hepatitis antigen is expressed in the product. After a recent report of patients developing Hepatitis B who had received Koāte HT (AHF), Lot 50P069, we repeated the routine release test for Hepatitis B Surface Antigen. As verification, this test, Radioimmune Assay (RIA), was performed in both Berkeley and Clayton. All results were negative. Further, none of the routine test requirements for documentation justifying release of the product indicated any potential for hepatitis B reactions.

As you know, regulations require, and we comply, that each unit collected at the plasma centers is tested for, among other things, the Hepatitis B surface antigen (HBsAg). If a unit is tested and is positive, the plasma center, by procedure, is directed to withdraw any such unit before shipment to the manufacturing plant. That unit is destroyed at the plasma center.

Discussions by Cutter were directed toward determining whether there were additional steps which could be imposed to further assure that none of our plasma-derived products include the HBsAg. It was decided to investigate the possibility of employing the RIA test on samples taken from pools used to produce product. The establishment of expertise and validation of technician technique was completed on 39 samples. To verify the validation, aliquots of retained samples of 39 plasma pools were recently tested; only one of the 39 pools tested positive and that was reaffirmed. The positive pool was included in the production of Koāte (AHF), Lot 50P069. At this time we cannot explain why this pool tested positive for HBsAg because of the rigid controls used in selecting plasma units for inclusion in a pool. This testing was done by the FDA approved method on all units used in the pool. All units were found non-reactive. Nevertheless, to further assure the integrity of plasma pools we implemented on December 15 pool testing by the RIA technique as a release specification in addition to routine release requirements for regulation products.

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With regard to this situation it is prudent and agreed to by our Director of Medical Services, Director of Quality Assurance, Director of Regulatory Affairs, Legal Counsel and Corporate Quality Assurance that all vials of this lot of Koāte® HT (AHF), Lot 50P069, be recalled and the returned product be destroyed in an appropriate manner with documented verification of this destruction.

According to U.S. procedures the attached list of documentation is required. Please proceed expeditiously in accordance with your country's regulatory requirements. You should provide a written reply with the required documentation with regard to this recall to Ms. Jean Huxsoll, Director of Quality Assurance Administration Services and Quality Engineering by December 30, 1986. Include copies of any correspondence to consignees and regulatory agencies regarding this recall.

GRO-C - Jean S Huxsoll

JS/mk