



Marketing Bulletin 5-85
26 June 1985



RE: Important Product Information Regarding
Non-Heat-Treated Antihemophilic Factor (Human),
Koate[®] and Fraction IX Complex, Konyne[®].

Dear Customer:

Effective immediately, no further export shipments of non-heat-treated Koate[®] or Konyne[®] will be made from U.S. distribution centers. We believe this action is in the best interests of the world hemophilia community and consistent with the data generated by Cutter in collaboration with outside research associates which demonstrate the safety and effectiveness of the Cutter heat treatment process. The United States Food and Drug Administration has been informed of this action.

We realize that it may not be feasible to immediately discontinue usage of non-heat-treated concentrates in some countries where registrations for heat-treated coagulation products have not yet been granted. However, we concur with those who recommend the use of heat-treated concentrates in preference to non-heat-treated concentrates and strongly encourage all responsible parties to make every effort to ensure local approval for sale of heat-treated Koate[®]-HT and Konyne[®]-HT.

Cutter historically has taken prudent action in response to the concerns of the hemophilia community regarding the relative safety of our products. We voluntarily intensified plasma donor screening procedures early in 1983 and later that year were the only U.S. commercial manufacturer to initiate plasma donor screening using testing for antibody to hepatitis core antigen. In 1984, we released the heat-treated Koate[®]-HT and Konyne[®]-HT, demonstrating that in the Cutter manufacturing processes, the concentrates are subjected to extended heat treatment in order to provide an added margin of safety. We are confident that sufficient research data have now been developed, leading toward the production of safe, stable concentrates without altering their effectiveness.

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Due to the rapid acceptance of information concerning the efficacy of heat treatment, we have experienced a large increase in demand for Koate[®]-HT and Konyne[®]-HT which has put a temporary strain on our ability to supply all markets; however, we will make every effort to meet your needs. Please contact your Cutter area management for answers to specific questions you may have regarding status of shipments and availability of heat-treated Koate-HT and Konyne-HT.

Regards,



W. P. DeHart
Group Product Manager

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