

Our Ref MWT/svs

8th January 1985.

Dr. A. Scott,
National Drugs Advisory Board,
63-64, Adelaide Road,
Dublin 2.

Dear Dr. Scott,

Thank you for your letter of 18th December, 1984, concerning the proposal that only heat-treated Factor VIII-containing preparations should be available on the market.

Cutter is moving towards total production of heat-treated Koate and we do not presently anticipate any future clinical use of the non-heat-treated product.

There are two reasons for this view:-

- a) Heat-treated Koate has been shown to be as safe and efficacious as the non-heated product in all studies conducted to date.
- b) It has been demonstrated that marker viruses (including A.I.D.S. related viruses) are inactivated by the heat-treatment method used for production of Koate-H.T.

Thus, with regard to the present state of knowledge we consider that since heat-treatment results in a product which is neither less safe nor less efficacious and which has a definite advantage over the non-heated product in terms of viral inactivation, there is no market for a product which has not been heat-treated.

Moreover, Cutter Laboratories consider that it is extremely unlikely that this situation will change.

Yours sincerely,

Marie W. Tatt (Mrs.),
Registration Manager.