Immuno Ltd



Arctic House, Rye Lane, Dunton Green, Nr Sevenoaks, Kent TN14 5HB

Telephone: Sevenoaks (0732) 458101 Telex: 95413 Fax No: (0732) 455175

Mr. D.G. Watters, General Secretary, The Haemophilia Society, 123 Westminster Bridge Road, London SE1 7HR. 10th February 1987 PJC/BMC

Dear David,

Thank you for your letter dated 2nd February 1987 concerning the warnings on the use of our blood products during recent years.

We have not issued promotional material on our coagulation concentrates which I assume is your main area of interest and, therefore, our warnings have been mainly restricted to the data sheet and the insert leaflet packed with the product.

As far as our non heat treated products were concerned, the only warning regarding viral inactivation was on hepatitis, as at that time this was thought to be the only problem that could be associated with blood products. I am enclosing a copy of our Kryobulin data sheet for our non heat treated product which was issued in March 1984 and contains our standard statement on hepatitis. This was issued from 1973 until the introduction of the heat treated products.

As soon as our dry heated product was introducted in March 1985 the statement was changed because of the problem with AIDS and I am enclosing a copy of the data sheet on our heat treated product dated March 1985. This statement is fairly clear in stating that although we have treated the product, the transmission of viral hepatitis or other viral infections cannot be excluded. You will also see on the front of the data sheet where it gives details of the heat treatment, it clearly states that this step is carried out to reduce the risk of transmission of infectious agents and not to eliminate them.

I hope this provides you with the information you require, but if I can be of any further help, please do not hesitate to contact me.

Yours sincerely, for IMMUNO LTD.

GRO-C

P.J. Coombes, Managing Director

Directors: N. Berry, F.P.S. (Chairman), P.J. Coombes, B.Pharm., M.P.S. (Managing), L. Fuchs (Swiss), R. Fuchs (Swiss), E.F. Weatherley Registered Office: Arctic House, Rye Lane, Dunton Green, Sevenoaks, Kent TN14 5HB. Registered in London Reg. No. 1040031