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19th July 1990

L.R. Whitbread Esq
Assistant Secretary
Committee on Safety of Medicines
Market Towers
1 Nine Elms Lane
London, SW8 5NG

Dear Mr. Whitbread,

HIV-2- Testing of Blood Donors

With reference to your letter dated 21st June, 1990, we have to advise you that we are not able to provide the confirmation that you requested.

As the files of the Licensing Authority will indicate, the blood products for which this company holds licences are products which are manufactured by the Cutter Biological Division of our parent company, Miles Inc, in the United States in accordance with all applicable requirements.

For the reasons set out in a letter dated 21st June, 1990, to all U.S. Registered Blood Establishments, the U.S. Food and Drug Administration takes the view that there is no public health need at this time to screen donors of blood or source plasma for antibodies to HIV-2. We enclose a copy of that letter.

Moreover, we wish to bring to your attention the fact that Cutter Biological (as well as others) have studied the susceptibility of HIV-2 to inactivation by a number of procedures and have found that it is inactivated rapidly, similar to HIV-1. We enclose a copy of a paper reporting these studies which were conducted on various plasma derived products made by Cutter Biological including Koate-HT and Gamimune-N. Given these results and the expectation that HIV-2 will partition similarly to HIV-1, it is concluded that, even if HIV-2 were to be present in a plasma pool, it would be removed and inactivated and that the resulting product would not transmit HIV-2 infection.

We enclose copies of three additional supporting papers.*

In the light of this information and the fact that we, in common we believe with other suppliers of blood products manufactured in the United States, are not able to provide the requested confirmation, we would welcome the opportunity to discuss this matter further.

Yours sincerely

G.C. Tuck
Company Secretary

*Schimpf, K. et al Absence of Anti-Human Immunodeficiency Virus Types 1 and 2 Seroconversion after Treatment of Haemophilia A or Von Willebrand's Disease with Pasteurised Factor VIII Concentrate. N. Engl J Med 1989; 321: 1148-1151

Busch, M.P et al. Monitoring Blood Donors for HIV-2 Infection by Testing Anti-HIV-1 Reactive Sera. Transfusion 1990; 30: 184-187.

Piszkiewicz, D. Inactivation of HIV-2 by Solvent/Detergent Treatment. Letter to the Editor, Transfusion 1990; 30: 192.

bcc:

Dr. R. Wheywell
Mr. C. Simpson