TRAVENOL

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19th December, 1984

Department of Health and Social Security,
Room 1022,
Medicines Division,
1 Nine Elms Lane,
Vauxhall,
London, SW8 5NQ.

Dear

RE: IN-VITRO DIAGNOSTIC KIT

It is our intention to import from the Travenol-Genentech Division of Travenol Laboratories, U.S.A., an in vitro diagnostic: the HTLV-III Antibody Enzyme immunoassay kit. This test provides a plasma screening procedure for HTLV-III virus, which is suspected of being involved in the aetiology of Acquired Immune Deficiency Syndrome (AIDS).

I understand that in vitro diagnostic kits do not require licencing in the U.K. However, the Office of Biologics of the F.D.A. (U.S.A.) do licence these kits and as the product is not yet approved in the U.S.A., the F.D.A. require a statement from the D.H.S.S. to the effect that in vitro diagnostics are not subject to licencing in the U.K.

I would be grateful if you could provide me with such a statement as we would like to start clinical trials in the U.K. as soon as possible. I enclose a proposed draft letter for your signature if it is acceptable.

I would appreciate your prompt attention to this matter.

Yours sincerely,
for TRAVENOL LABORATORIES Ltd.

B.Sc.,Ph.D.,M.I.Biol.,F.I.M.L.S.
Regulatory Affairs Manager