TRAVENOL

Travenol Laboratories Ltd.,
Caxton Way, Thetford,
Norfolk. IP24 3SE Great Britain
Telephone: Thetford (0842) 4581
Telex: GRO-C
Fax: (0842) 2219

IJB/MES

16th April, 1987

Variations Section,
National Drugs Advisory Board,
63-64 Adelaide Road,
Dublin 2,
Eire.

Dear Sir,

1. PLASMA PROTEIN FRACTION 5% W/V - PA.167/59/1 (RA.542)
2. BUMINATE 5% W/V HUMAN ALBUMIN FRACTION - PA.167/1/3-5 (RA.410)
3. BUMINATE 20% W/V HUMAN ALBUMIN - PA.167/1/1-2 (RA.378)
4. HAEMOFIL HT ANTIHAEMOPHYLIC FACTOR (HUMAN) METHOD FOUR, DRIED, HEAT TREATED - PA.167/7/8-13 (RA.470)

Please find enclosed two copies of notifications of change to the Product Licences referenced above to include specification that products are manufactured exclusively from individual plasma donations tested and found non-reactive for HTLV-III antibody and that plasma is collected only from donors found to have normal levels of alanine aminotransferase (ALT).

The test methodology for determination of the presence of Hepatitis B Surface Antigen (HBsAG) and HTLV-III antibody and plasma levels of ALT is appended as Attachments I-III, consisting, in each case, of the Travenol Standard Operating Procedure and the relevant test manufacturer's operating manual.

If you require any further information with regard to the above, please do not hesitate to contact me.

Yours sincerely,
for TRAVENOL LABORATORIES Ltd.

GRO-C

Ivan J. Bryant
Regulatory Officer, B.Sc., C.Biol., M.I.Biol.