Interoffice correspondence

TRAVENOL

Travenol Laboratories Ltd.,
Caxton Way, Thetford,
Norfolk, IP24 3SE, Great Britain
Telephone: Thetford (0842) 4581

LA-297

to: See Distribution

date: 10th December, 1986

from: David Barrow

copies: See Copy Distribution

subject: EUROPEAN PHARMACOPOEIA - SCREENING OF PLASMA DONATIONS USED IN THE MANUFACTURE OF ALBUMIN PRODUCTS

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With effect from 1st January, 1987, European Pharmacopoeial Monographs for Human Albumin Solution and Human Plasma Protein Solution will specify that source plasma be tested for the presence of Hepatitis B surface antigen and HTLV-III antibodies.

Whilst Travenol do not claim that Plasma Protein Fraction 5%, BUMINATE 5% Human Albumin Fraction or BUMINATE 20% Human Albumin comply with European Pharmacopoeial Monographs, it is already an U.K. and, since product for Ireland must be released by the U.K. N.I.B.S.C., an Irish regulatory requirement that all blood products including albumin products be manufactured exclusively from individual plasma donations screened for the presence of HTLV-III antibodies.

- See my letter to Dr. Duncan Thomas of the U.K., N.I.B.S.C. of 11th November, 1986 (appended).

GRO-C

David M. Barrow