bxc: T. Andary
C. Brooks
D. Castaldi
H. Kingdon
R. Patterson - DF
B. Rain - DF
J. Wohlreich - LC

HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC

P.O. Box 1878
Glendale, California 91202-2936, U.S.A.
818-956-2200

June 11, 1985

Elaine C. Esber, M.D.
Director
Office of Biologics Research
and Review HFN-825
Division of Product Certification
Center for Drugs and Biologics
8800 Rockville Pike
Bethesda, MD 20205

Dear Dr. Esber:

As of this date, Hyland Therapeutic Division of Travenol Laboratories, Inc. will cease production and distribution of non-treated Anti(Hemophilic Factor (Human), HEMOFIL® and Factor IX Complex, PROPLEX®SX. We, therefore, wish to amend our licenses for Anti(Hemophilic Factor (Human) and Factor IX Complex, Sephadex Exchange Method to make the heat treatment step mandatory for these products.

Further, we wish to inform you that, consistent with the decision that it is no longer in the public interest to market these products, as of this date, we are withdrawing non-treated Anti(Hemophilic Factor (Human), HEMOFIL® and Factor IX Complex, PROPLEX®SX from the market.

Those coagulation products which are derived from Cohn fraction intermediates (Factor IX Complex, PROPLEX® and Anti-Inhibitor Coagulant Complex, AUTOPLEX®) are not included in these actions since they are obtained from an alcohol derived fraction and there are no treated substitutes available.

If you have any questions regarding this request, please do not hesitate to contact me or my staff at (818) 507-5522.

Sincerely,

GRO-C

Stephen L. Holst
Director of Regulatory Affairs

nsl/wd002

EXHIBIT 46