Authorized June 4, 1985

HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC.

P.O. Box 1976
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Glendale, California 91209-2806, U.S.A.
818-956-6300

MARKET WITHDRAWAL MARKET WITHDRAWAL MARKET WITHDRAWAL

GRO-C

June 3, 1985

RE: Non-Treated Antihemophilic Factor (Human), HEMOFIL® and Factor IX Complex, PROPLEX®SX

Dear Customer:

Hyland Therapeutics Division of Travenol Laboratories, Inc. has discontinued the production and distribution of non-treated Antihemophilic Factor (Human), HEMOFIL® and Factor IX Complex, PROPLEX®SX and is withdrawing these products from the market.

From the weight of preliminary data, the perception of the medical community is that the use of treated products carries less risk of transmission of Acquired Immune Deficiency Syndrome (AIDS). While there is presently no clear scientific evidence that either Antihemophilic Factor (Human), HEMOFIL or Factor IX Complex, PROPLEX®SX is involved in such transmission, we believe that it is in the best interests of the Hemophilia community for us to recover any unused units of these products and replace them with treated products for the following reasons.

1. Equivalent treated products, which offer greater assurance of safety, are currently available, i.e. HEMOFIL®T and PROPLEX®SX-T.

2. The National Hemophilia Foundation and others have recommended that treated products be used in preference to non-treated products on the basis of increased safety.

Attached is a list of unexpired HEMOFIL® and PROPLEX®SX lots which may be in your possession. Please compare these lot numbers with the lot number(s) of HEMOFIL® and PROPLEX®SX in your inventory. Any product which is in your possession and is on the attached list should be placed in quarantine until arrangements can be made to have it returned to us.

If you have product which is from the affected lots, Hyland will arrange to have it picked up at a location specified by you and will replace it with treated product.

We asked that you complete the information required on the attached form and return it to us in the enclosed envelope at your earliest convenience.

MDL BAX027224
CONFIDENTIAL

If you have any questions, or need emergency product, please call Robert Bronaugh:

within California -- GRO-C
outside California --

We appreciate your prompt cooperation in this matter and apologize for any inconvenience.

The United States Food and Drug Administration has been advised of this action.

Very truly yours,

GRO-C

Stephen L. Holst
Director of Regulatory Affairs

nsl/wd001
Attachments