To: Bob Lutz
FYI
able

HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC.

P.O. Box 1976
444 West Glencoe Blvd.
Glendale, California 91202-2938, U.S.A.
818-956-3200

D

R.W. LUTZ

5

MARKET WITHDRAWAL MARKET WITHDRAWAL MARKET WITHDRAWAL

JUN 2 4 1985

June 11, 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 all non-treated Antihemophilic Factor (Human), HEMOFIL® and Factor IX Complex, PROPLEX®SX and is withdrawing these products from the market.

On the basis of data currently available, we have concluded that the use of treated products carries less risk of transmission of Acquired Immunodeficiency Syndrome (AIDS). While there is presently no conclusive 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. Treated products, which are likely to 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 according to our records may be in your possession. Please compare these lot numbers with the lot number(s) of HEMOFIL® and/or PROPLEX®SX in your inventory. Any product which is in your possession or that of your home care patients, and is on the attached list should be placed in quarantine and held until Hyland notifies you of the correct return procedure.

RFA 068733

If you have product which is from the subject lots or have provided your home care patients with product from these lots, Hyland will arrange to have it picked up at a location specified by you and will replace it with treated product.

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

A 068439

06/11 15:21 GRO-C #02 EXHIBIT 48

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

within California -- 1-800-GRO-C
outside California -- 1-800-GRO-C

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

RFA 068734

A 068440

06/11 15:22 GRO-C #03 OF 03