HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC.

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September 2, 1983

John C. Petricciani, M.D.
Director
Office of Biologics HFN-810
Division of Compliance
National Center for Drugs and Biologics
8800 Rockville Pike
Bethesda, MD 20205

Dear Dr. Petricciani:

Recently we were notified by the American National Red Cross that an individual who donated whole blood in one of their Southern California centers in July, 1982 died of Acquired Immune Deficiency Syndrome (AIDS) in May, 1983. They informed us that the plasma from that donor's whole blood unit had been sent to us for processing in July of 1982.

After a number of conversations with the American National Red Cross, the Centers for Disease Control, and the physicians who treated the donor during his illness, we are convinced that this individual did in fact have AIDS.

Our records show that the pool containing this plasma was processed to Antihemophilic Factor (Human) and Factor IX Complex (Human). In addition, several lots of Normal Serum Albumin (Human) and Immune Serum Globulin (Human) were manufactured from the pool. The AHF and NSA lots were distributed by the Red Cross while the Factor IX and ISG were distributed by Hyland Therapeutics.

Although there is at present no clear scientific evidence linking the transmission of AIDS to Blood Products, it is Travenol's position that under the present circumstances, recall of untreated coagulation products represents a prudent course of action. We therefore initiated a voluntary recall of two lots of Factor IX Complex (Human) on August 25, 1983.

In separate action, the American National Red Cross recalled the two lots of Antihemophilic Factor (Human) which were manufactured from the affected pool.

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Prior to initiating the recall, I called Sammie Young, Director of the Division of Compliance and Madge Crouch, Acting Deputy Director of the Office of Biologics, to discuss the circumstances and advise them of our intentions.

On Monday, August 29, 1983, I met with Mr. W. R. Teachworth of the Los Angeles District Office of the Food and Drug Administration. Particulars of the recall including a sample of the Recall Letter and the labeling wich was used on the recalled lots were furnished to Mr. Teachworth. Subsequently, at Mr. Teachworth's request, he was provided with copies of processing records establishing the traceability of all products manufactured from the involved plasma pool.

Tracing

At this time, we are not contemplating recall of the Immune Serum Globulin (Human) manufactured from the pool. It is our observation that the concerns which have been voiced by the scientific community regarding the safety of Blood Products manufactured from pools containing plasma at increased risk for AIDS have been directed toward the coagulation products - particularly Factor VIII. In our opinion, there would be little, if any, scientific support for a recall of Immune Serum Globulin, Normal Serum Albumin or Plasma Protein Fraction. It is our understanding that the Red Cross has also arrived at this conclusion and does not intend to recall the albumin manufactured from this pool.

If I can be of any further service, please feel free to call.

Sincerely,

GRO-C

William R. Srigley
Director of Regulatory Affairs
and Quality Control

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Attachment

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