Public Health Service

Food and Drug Administration Bethesda, MD 20205

March 21, 1983

Our Reference: 82-196

Michael B. Rodell, Ph.D.
Travenol Laboratories, Inc.
Hyland Therapeutics Division
444 West Glenoaks Boulevard
Glendale, CA 91202

Dear Dr. Rodell:

The amendment to your product license for Antihemophilic Factor (Human) to allow for an optional heat treatment of final containers has been approved. This information will be made a part of your files.

Please submit stability data for the six month and twelve month intervals and then the subsequent information as it becomes available.

Sincerely yours,

John C. Petricciani, M.D.
Director
Office of Biologics

National Center for Drugs and Biologics

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