

"CONFIDENTIAL - MDL 986"

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Bethesda, MD 20205

September 5, 1985

Steven J. Ojala, Ph.D.
Miles Laboratories, Inc.
4th & Parker Streets
P.O. Box 1986
Berkeley, CA 94701

In reply refer to: HFN-825

Dear Dr. Ojala:

We have received your letter of August 9 informing us that you are no longer manufacturing or distributing non-heat treated Antihemophilic Factor (Human) and non-heat treated Factor IX Complex.

As noted in your letter, you have informed your customers and recommended that they review their product inventory and return all non-heat treated product.

Sincerely yours,

Elaine C. Esber, M.D.
Director
Office of Biologics Research and Review
Center for Drugs and Biologics

MDA001697