DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Bethesda MD 20205

February 29, 1984

Our Reference: 83-481

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

Dear Dr. Ojala:

The amendment to your Antihemophilic Factor (Human) product license, to include a heat treatment step as described in your submission of November 21, 1983, has been approved. This information will be incorporated into your product license file.

Final evaluation of the effect upon potential infectivity will be determined in prospective studies and from the results of your ongoing studies in chimpanzees. Please submit the preliminary results of these studies as they become available.

The dating period for this product shall be two years from the date of the last valid potency test when stored at 2-8 °C. Within this period the product may be stored at room temperature not to exceed 25 °C for up to three months.

Please submit the results of the ongoing stability study on lot 58505 at six months and yearly thereafter. In addition, please place the first full production lot on stability and submit the results to the Office of Biologics Research and Review at three and six months and then annually throughout the dating.

You are requested to submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information. In addition, we request that advertising and promotional labeling be submitted for review at the time of initial dissemination.

Sincerely yours,

Mindy L. Cranek

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

Paul Parkman

for Harry M. Meyer, Jr., M.D.
Director
National Center for Drugs and Biologics

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