REVLON HEALTH CARE GROUP
ETHICAL PRODUCTS DIVISION
303 SOUTH BROADWAY, TARRYTOWN, NY 10591 (914) 631-5850

MICHAEL B. RODELL, Ph.D.
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

CERTIFIED MAIL

July 12, 1985

Elaine C. Esber, M.D.
Director
Office of Biologics Research and Review - HFN-800
Center for Drugs and Biologics
Food and Drug Administration
8800 Rockville Pike
Bethesda, Maryland 20205

Dear Dr. Esber:

During a meeting held at the Office of Biologics Research and Review on June 17, 1985, you requested manufacturers of Antihemophilic Factor (Human) and Factor IX Complex (Human) to provide information as to their policies regarding the manufacture and distribution of product not subjected to viral inactivation procedures.

This is to advise you that Armour Pharmaceutical Company no longer manufactures or distributes untreated Antihemophilic Factor (Human) for domestic utilization. We will continue to export unlabeled final containers of untreated Antihemophilic Factor (Human) to our affiliate company in Germany for heat treatment at that site, in order to meet scheduling and marketing needs in an expeditious manner.

Since we do not yet have approval from you to employ heat treatment in the manufacture of Factor IX Complex (Human), we have not ceased production and distribution of untreated product. We are currently trying to obtain HTLV-III/LAV inactivation data for the heat treatment condition used in order to comply with the request made in your letter of February 21, 1985.

Sincerely,

GRO-C

Michael B. Rodell, Ph.D.

MBR:ag

ARMOUR PHARMACEUTICAL COMPANY

USV LABORATORIES

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