

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 02 1985

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(7295)

Michael B. Rodell, Ph.D.  
Armour Pharmaceutical Company  
303 South Broadway  
Tarrytown, NY 10591

In reply refer to: HFN-825

Dear Dr. Rodell:

We have received your letter of July 12 informing us that you are no longer manufacturing or distributing non-heat treated Antihemophilic Factor (Human) for domestic utilization. However, in order to meet scheduling and marketing needs you plan to continue to export unlabeled final containers of non-heat treated Antihemophilic Factor (Human) to your affiliate company in Germany for heat treatment at that site.

It is requested that you notify this office if you plan to export non-heat treated Antihemophilic Factor to other than your affiliate company in Germany. Such notification should be made prior to any shipment of the product.

As noted in your letter, you are continuing to manufacture and distribute your non-heat treated Factor IX Complex. We look forward to receiving your HTLV-III viral inactivation data so that we may continue the review of your submission for the heat treatment of Factor IX Complex.

Sincerely yours,

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

cc: Ms. Crouch, HFN-802  
A. Hoppe, HFN-830  
Dr. Aronson, HFN-830  
C. Brooks, HFN-830  
D. Parshall, HFN-895

PREPARED BY:HFN-825:JBAGLEY:mn 7-24-85 (0627V)

EXHIBIT 47

FDA 005064

FILE  
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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-825	GRO-C	7/29/85	HFN-825	GRO-C	8/2/85			
HFN-825	GRO-C	7/19/85						

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