

PHF HT



ARMOUR
PHARMACEUTICAL
COMPANY

ONE SENTRY PLAZA, SUITE 4000, BLUE BELL, PA 19422

October 10, 1986

Attention: Blood Bank Director or Hemophilia Treatment Coordinator

Dear Colleague:

Armour Pharmaceutical Company brought to your attention in June, 1986 three instances in which hemophiliacs tested positive for HIV antibody subsequent to the administration of H.T. FACTORATE Antihemophilic Factor (Human) Dried, Heat-Treated derived from plasma not tested for this antibody. Armour also reported the confounding circumstances surrounding each of those seroconversion incidents.

As previously stated, Armour Pharmaceutical Company will continue to openly discuss issues associated with the care and treatment of the hemophiliac. On September 29, 1986, a United Kingdom physician informed Armour of two additional seroconversions following the administration of H.T. FACTORATE concentrate that was manufactured from donor plasma that, again, was not tested for the HIV antibody. The use of this material occurred prior to Armour's exchange program initiated last Spring.

Armour immediately notified and met with the Department of Health and Social Security (DHSS), the UK equivalent of the FDA. During that meeting, DHSS requested Armour to withdraw all antihemophilic factor concentrates from the United Kingdom effective October 6, 1986. We complied with their request. To date, there have been no reported seroconversions either in the U.S. or abroad with our H.T. FACTORATE concentrate that has been obtained from donors who were tested for the HIV antibody.

Armour is rigorously investigating all data concerning these two patients and their medical treatment. We have met with representatives of the Office of Biologics Research and Review, Food and Drug Administration to discuss the issue; agreement was reached that insufficient information exists to warrant a product withdrawal. The FDA stressed the need to obtain additional information and data regarding the patients in question.

The Office of Biologics Research and Review will consult with leading members of the hemophilia community, prior to making a determination of what course of action to pursue.

71595

MDL 986

RFA 063773

EXHIBIT 102

ACC8849

In our letter of June 23rd, Armour informed you of an exchange program to replace existing inventories of unscreened material with H.T. FACTORATE concentrate that is donor tested for the HIV antibody. To the best of our knowledge all non-screened H.T. FACTORATE has been exchanged and we believe that no inventories exist within the normal channels of distribution. However, we cannot definitively exclude the possibility that some such product might still remain in the channels of distribution. Therefore, we again urge you to examine your inventory to confirm that no unscreened material exists. In the event you do have unscreened material we urge you not to use it; any such product will be replaced by Armour. In the latter event, please contact your local Armour Representative or Technical Coagulation Specialist. Attached are the lot numbers of unscreened material for your convenience.

Armour Pharmaceutical Company believes that the general wellbeing and health care of the hemophilia patient take the highest priority, and we will continue to keep you informed of all future developments.

Sincerely,

GRO-C

/ Michael B. Rodell, Ph.D.
Vice President
Scientific Affairs

Att.

71596

-2-

RFA 063774

A008850

H.T. FACTRATE ANTIHEMOPHILIC FACTOR (HUMAN), HEAT-TREATED

Product Manufactured from Plasma Not Tested for Anti-HTLV-III

<u>Lot No.</u>	<u>Exp. Date</u>	<u>Lot No.</u>	<u>Exp. Date</u>
Y80105	June 25, 1986	Y90809	October 6, 1986
Y12506	June 27, 1986	Y91109	October 8, 1986
Y11606	June 27, 1986	Y73703	October 9, 1986
Y11204	June 30, 1986	Y10309	October 9, 1986
Y80005	July 2, 1986	Y14109	October 11, 1986
Y12708	July 3, 1986	Y33709	October 16, 1986
Y12606	July 10, 1986	Y10409	October 17, 1986
Y11706	July 13, 1986	Y92409	October 24, 1986
Y80806	July 19, 1986	Y92609	October 24, 1986
Y85507	August 6, 1986	Y92709	October 24, 1986
Y80605	August 8, 1986	Y10510	October 25, 1986
Y11907	August 10, 1986	Y91709	October 29, 1986
Y14307	August 10, 1986	Y93810	October 29, 1986
Y11807	August 16, 1986	Y11010	October 30, 1986
Y12007	August 16, 1986	Y93410	November 1, 1986
Y12108	August 29, 1986	Y93710	November 1, 1986
Y87308	August 31, 1986	Y94610	November 2, 1986
Y10108	September 4, 1986	Y11110	November 3, 1986
Y85407	September 4, 1986	Y94510	November 5, 1986
Y10009	September 22, 1986	Y94310	November 7, 1986
Y89608	September 25, 1986	Y94710	November 14, 1986
Y89708	September 25, 1986	Y95110	November 15, 1986
Y10209	September 26, 1986	Y93510	November 15, 1986
Y88208	September 27, 1986	Y94810	November 16, 1986
Y90709	October 2, 1986	Y96010	November 16, 1986

71597

RFA 063775

A008851

H.T. FACTORATE ANTIHEMOPHILIC FACTOR (HUMAN), HEAT-TREATED

Product Manufactured from Plasma Not Tested for Anti-HTLV-III (Continued)

<u>Lot No.</u>	<u>Exp. Date</u>	<u>Lot No.</u>	<u>Exp. Date</u>
Y96111	November 16, 1986	Y99412	January 10, 1987
Y95310	November 19, 1986	Y99612	January 10, 1987
Y95410	November 20, 1986	Y13011	January 11, 1987
Y33810	November 21, 1986	Y96211	January 11, 1987
Y95510	December 4, 1986	Y97611	January 12, 1987
Y96611	December 12, 1986	Y99512	January 12, 1987
Y96711	December 12, 1986	Y94110	January 14, 1987
Y97311	December 12, 1986	Y98511	January 16, 1987
Y96511	December 17, 1986	Y97211	January 17, 1987
Y97411	December 17, 1986	Y99812	January 17, 1987
Y97711	December 17, 1986	Y99912	January 18, 1987
Y97811	December 17, 1986	Y97511	January 19, 1987
Y97911	December 17, 1986	Y97011	January 22, 1987
Y98011	December 19, 1986	Y96311	January 22, 1987
Y98411	December 27, 1986	A10601	January 31, 1987
Y98912	January 2, 1987	A13401	February 4, 1987
Y99212	January 7, 1987	A10901	February 6, 1987
Y98311	January 8, 1987	A13201	February 6, 1987
Y97911	January 8, 1987	A12201	February 11, 1987
Y97111	January 9, 1987	A13101	February 11, 1987
Y99712	January 9, 1987	A13301	February 12, 1987
Y96411	January 10, 1987	A13601	February 12, 1987
Y98711	January 10, 1987	A13701	February 12, 1987

H.T. FACTORATE ANTIHEMOPHILIC FACTOR (HLMAN), HEAT-TREATED

Product Manufactured from Plasma Not Tested for Anti-HTLV-III (Continued)

<u>Lot No.</u>	<u>Exp. Date</u>	<u>Lot No.</u>	<u>Exp. Date</u>
A13901	February 18, 1987	A17802	March 10, 1987
A15001	February 20, 1987	A16802	March 11, 1987
A10801	February 20, 1987	A17202	March 11, 1987
A14701	February 21, 1987	A17402	March 11, 1987
A15101	February 21, 1987	A17502	March 11, 1987
A15201	February 21, 1987	A17602	March 11, 1987
A16501	February 21, 1987	A18802	March 11, 1987
A14601	February 26, 1987	A17902	March 12, 1987
A14801	February 26, 1987	A18702	March 15, 1987
A14901	February 26, 1987	A18902	March 15, 1987
A13801	February 27, 1987	A18502	March 18, 1987
A15301	February 27, 1987	A18402	March 19, 1987
A15801	February 27, 1987	A19102	March 19, 1987
A15901	February 28, 1987	A106203	March 22, 1987
A15601	March 2, 1987	A19202	March 25, 1987
A16902	March 4, 1987	A19503	March 26, 1987
A15501	March 5, 1987	A19903	March 26, 1987
A16202	March 5, 1987	A17702	March 28, 1987
A16301	March 6, 1987	A19703	April 1, 1987
A16702	March 6, 1987	A19803	April 1, 1987
A17302	March 6, 1987	A105903	April 1, 1987
A17002	March 7, 1987	A20203	April 4, 1987
A33602	March 8, 1987		

H.T. FACTORATE ANTIHEMOPHILIC FACTOR (HUMAN), HEAT-TREATED

Product Manufactured from Plasma Not Tested for Anti-HTLV-III (Continued)

<u>Lot No.</u>	<u>Exp. Date</u>	<u>Lot No.</u>	<u>Exp. Date</u>
A20403	April 8, 1987	A23304	May 14, 1987
A20803	April 8, 1987	A23204	May 15, 1987
A20103	April 9, 1987	A23904	May 15, 1987
A20603	April 9, 1987	A24304	May 16, 1987
A20903	April 12, 1987	A24704	May 16, 1987
A21103	April 12, 1987	A24004	May 20, 1987
A20003	April 16, 1987	A24504	May 22, 1987
A21603	April 16, 1987	A24104	May 22, 1987
A21503	April 17, 1987	A24804	May 23, 1987
A21303	April 18, 1987	A24404	May 24, 1987
A22203	April 18, 1987	A25705	May 29, 1987
A21403	April 23, 1987	A25505	May 30, 1987
A21703	April 23, 1987	A34005	May 30, 1987
A21803	April 23, 1987	A25104	May 31, 1987
A22704	April 25, 1987	A25905	June 3, 1987
A22904	April 25, 1987	A26205	June 4, 1987
A22504	April 26, 1987	A25605	June 5, 1987
A23104	April 30, 1987	A25805	June 5, 1987
A22604	May 3, 1987	A21904	June 6, 1987
A23004	May 8, 1987	A25004	June 6, 1987
A22303	May 8, 1987	A26605	June 15, 1987
A22103	May 10, 1987	A26705	June 19, 1987
A23404	May 10, 1987	A26805	June 19, 1987
A23804	May 13, 1987	A106505	June 20, 1987
A23704	May 14, 1987	A27305	June 21, 1987

71600

RFA 063778

A008854

H.T. FACTORATE ANTIHEMOPHILIC FACTOR (HLMAN), HEAT TREATED

Product Manufactured from Plasma Not Tested for Anti-HTLV-III (Continued)

<u>Lot No.</u>	<u>Exp. Date</u>
A27705	June 21, 1987
A27005	June 25, 1987
A28005	June 25, 1987
A28506	June 28, 1987
A23906	July 24, 1987
A31507	August 8, 1987
A33207	August 26, 1987
A34107	August 26, 1987
Y33908	August 27, 1987
A35208	September 5, 1987
A106708	September 12, 1987
A35308	September 19, 1987
A30106	September 25, 1987
A106609	October 1, 1987
A106809	October 29, 1987

71601

-7-

RFA 063780

A008855

