

Cutter

FC
MILES
[Signature]

TO: See Distribution

DATE: November 4, 1983

FROM: Jean F. Huxsoll - QA
SUBJECT: Recall on Koāte® and Konŷne® with AIDS Donor - Status Report No. 1

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On October 31, 1983, it was decided that Cutter would voluntarily recall one lot of Konŷne® and 15 lots of Koāte®. These lots contained plasma from a donor who was diagnosed as having AIDS after his last donation. The donations were from November, 1982, to September, 1983, as detailed in Attachment I.

Attachment II summarizes the individual coagulation lots with the number of vials on hand and those distributed. In total, 51 million units of AHF have potential involvement.

*where does this come from **

The individual Fraction II material is summarized in Attachment III. No Fraction II final container lots were distributed from the pools involved.

Attachment IV is a copy of the recall letter sent to all domestic consignees. 60,063 vials of Koāte® and 4606 vials of Konŷne® were distributed to 304 domestic consignees and 14 international consignees including Canada, France, Jordan, Israel, Taiwan, Singapore, Philippines, Indonesia, Japan, Columbia, Venezuela, Costa Rica, Argentina, and Italy. Letters were also sent to the 278 Hemophilia Treatment Centers in the United States.

JFH:crn
attachments
11/04/83:0036

* From Jean Huxsoll
total units involved, whether distributed or not
3 page only calculates number of units distributed
[Signature: Jean F. Huxsoll]

RECEIVED

NOV 07 1983

J. D. RYAN

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DONOR HISTORY

BLEED DATE	CONTROL NO.	DATE SHIPPED	POOL NO.	AHF LOT NO.	NO. VIALS DISTRIBUTED	PTC LOT NO.	NO. VIALS DISTRIBUTED	FR. 11 LOT NO.
11/18/82	230479	11/30/82	PF1281	NC8461 NC8458	5,424 5,236	NC9117	4,606	PF1281
11/30/82	230955	12/14/82	PF1290	NC8460	5,094	None		EP1242
12/02/82	231015	12/14/82						
12/07/82	231280	12/14/82	PF1287	NC8456	See Above	None Released		BX6319 BX6320
12/09/82	231348	12/14/82						
12/14/82	231636	12/28/82	PF1298	NC8462	5,713	None		EP1248
12/16/82	231703	12/28/82						
12/21/82	231961	01/11/83						
12/28/82	600023	01/11/83						
12/30/82	600123	01/11/83	PF1309	NC8465	2,425	None		EP1242
01/04/83	600367	01/11/83		NC8466	3,050	None		
01/06/83	600385	01/11/83						
01/11/83	600646	01/25/83						
01/13/83	600705	01/25/83	PF1320	NC8470	4,998	None		EP1238
01/18/83	600973	01/25/83						
01/20/83	601049	01/25/83						
01/27/83	601428	02/08/83	PF1334	NC8474 NC8475	5,135 8,634	None		EP1238
01/31/83	965754	02/08/83	PF1339	NC8476	5,779	NC9120	0	BX6319 BX6320
02/03/84	965805	02/08/83						
02/08/83	965890	02/22/83						
02/10/83	965914	02/22/83	PF1343	NC8477	2,592	None		EP4029 BX6311
02/13/83	965991	02/22/83						
02/17/83	966031	02/22/83						
02/24/83	966133	03/07/83						
02/28/83	966200	03/07/83	PF1353	NC8479	479	None		EP4028
03/03/83	966252	03/07/83		NC8480	4,631			
03/08/83	966317	03/21/83						
03/10/83	966335	03/21/83	PF1375	NC8493	3,729	NC9133	0	EP4029
03/17/83	966436	03/21/83						
03/28/83	966376	04/05/83	PF1385	NC8489	229	None		EP4032
03/31/83	966640	04/05/83						
06/30/83	336184	07/12/83						
07/05/83	336297	07/12/83	PF1461	58514	0	None Released		BX5327
07/07/83	336368	07/12/83						
07/12/83	336603	07/29/83						
07/15/83	336687	07/29/83	PF1477	SD1477/1478	0	None		BS5249
07/19/83	336866	07/29/83						
07/22/83	337018	07/29/83						
07/26/83	337182	08/09/83						
07/29/83	337314	08/09/83						
08/02/83	337433	08/09/83	PF1496	58521	0	None		PF1496
08/08/83	337617	08/23/83						
08/11/83	337755	08/23/83						
08/22/83	338120	09/05/83	PF1511	NC8527	0	NC9136 PF1511	0 0	PF1511
08/25/83	338272	09/05/83						
09/09/83	338696	09/20/83						
09/13/83	338835	09/20/83	PF1520	PF1520	0	None		EP1281
09/16/83	338956	09/20/83						

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COAGULATION PRODUCTS WITH DONOR PROBLEM

LOT NO.	PRODUCT CODE	RELEASE DATE	NUMBER RELEASED	ON HOLD	DISTRIBUTED	UNITAGE	AHF UNITS (In Millions)
NC8458	650-30	03/02/83	5239		5239	510	2.672
NC8460	650-30	03/02/83	5104	3	5101	540	2.755
NC8461	650-30	03/02/83	5760	336	5424	590	3.200
NC8462	650-70	03/14/83	7483	4865	2618	270	0.707
NC8465	650-72	03/08/83	5034	2609	2425	580	1.407
NC8466	650-71	03/18/83	6700	3650	3050	280	0.854
NC8470	650-30	03/28/83	2381	683	1698		
	650-77	10/12/83	3300		3300	640	3.199
	650-77	Not Rel.	159		0		
NC8474	650-30	04/15/83	5135		5135	560	2.876
NC8475	650-20	04/19/83	6047		6047		
	650-20S	04/19/83	1998	931	1067		
	650-76	05/05/83	1005		1005	280	2.418
	650-76	09/21/83	515		515		
NC8476	650-20	04/20/83	7198	1419	5779	290	1.676
NC8477	650-50	04/26/83	2807	215	2592	1190	3.084
NC8479	650-30Z	06/27/83	5533	5054	479	600	0.287
NC8480	650-30Z	06/29/83	3459	818	2641		
	650-77	06/29/83	1990		1990	510	2.362
NC8489	650-30Z	07/01/83	4955	4726	229	690	0.158
NC8493	650-20Z	07/20/83	7544	3815	3729	250	0.932
TOTAL				29124	60063		28.587
S8514	Not Released			1854	Glycine Precipitated		2.651
S8521	Not Released			1442	Glycine Precipitated		1.990
NC8527	Not Released			1843	German		2.765
SD1477/	Not Released			29.86 kg	Glycine Precipitated		
1478							1.509
PF1520	Not Released			24.31 kg			
TOTAL							8.915
NC9117	620-20	03/28/83	4606		4606		
NC9119	Not Released			None			
NC9120	Not Released			5668	Released by OB; Not Packaged		
NC9133	Not Released			5192	Submitted to OB		
NC9134	Not Released			3953			
NC9136	Not Released			5079	On Test; Not Submitted		
PF1511	Not Released			1.24 kg			

JFH:crn:11/04/83

CUTTER LABORATORIES
 1455 LABORATORY DR.
 1000 HUNTERS STREET
 POST OFFICE BOX 1411
 CHESTERVILLE, CALIFORNIA 94627
 (415) 251-1888
 DIRECT DIAL (415) 251-1726

Notice: Info product was received for recall.
 TELE CUTTER (415) 251-1726
 October 31, 1983

URGENT DRUG RECALL

RE: Koznes Factor IX Complex (Human)
 Lot Product Code
 1/27 NC 9117 620-20

Koznes Antihemophilic Factor (Human)							
Lot	Product Code	Lot	Product Code	Lot	Product Code	Lot	Product Code
2/2/83 NC 8458	650-30	2/2 NC 8460	650-30	2/2 NC 8461	650-30		
2/14 NC 8462	650-70	2/18 NC 8470	650-30	2/18 NC 8474	650-30		
4/19 NC 8475	650-20	4/19 NC 8476	650-20	4/19 NC 8477	650-50		
4/19 NC 8479	650-30Z	4/19 NC 8480	650-30Z	4/19 NC 8489	650-30Z		
4/19 NC 8493	650-20Z						

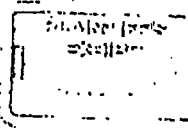
The purpose of this letter is to make you aware that the above lots contain plasma donated from an individual who subsequently was diagnosed as having Acquired Immune Deficiency Syndrome (A.I.D.S.).

Cutter is voluntarily withdrawing this material as a precautionary measure, as there is no evidence that these products will transmit the disease. No adverse reactions involving these lots have been reported.

Please examine your stock immediately to determine if you have any of the above lots on hand, and promptly return all units via UPS to the nearest Distribution Center:

Cutter Distribution Center
 15320 East Salt Lake Avenue
 City of Industry, CA 91744
 ATTENTION: RECALL COORDINATOR

Cutter Distribution Center
 6135 Purdue Drive
 Atlanta, GA 30336
 ATTENTION: RECALL COORDINATOR



Please institute similar measures to assure that all recipients of the above material from you are notified and arrangements made for return of all units.

You will be credited for your returned goods and the postage. Would you please return the enclosed postcard immediately providing the requested information.

This recall is being made with the knowledge of the Food and Drug Administration. If you have any questions, please contact our coordinator, Jean Huxsolt, at (415) 420-5134. Thank you for your assistance.

831031 NC 201

Sincerely,
John H. Cherry
 John H. Cherry
 Director, Group Quality Assurance
 100026