

# CSL Behring

## RETURNED GOODS FORM

ATTENTION: CUSTOMER

To expedite the processing of your credit, please check your inventory of Monoclote-P®, lots J91504, J91604, J91705, J91806, complete this form and return with your shipment.

**Note:** You will be reimbursed for your actual product cost and shipping charges.

Antihemophilic Factor (Human)

Monoclote-P®

NDC 0053-7656-04

<b>Lots:</b>	J91504	exp.	April 25, 2010
	J91604	exp.	April 30, 2010
	J91705	exp.	May 2, 2010
	J91806	exp.	June 9, 2010

QUANTITY (each) \*\*

**\*\*When listing quantity, please count individual vials.**

Indirect customers will be credited through their distributor.

Please indicate your distributor \_\_\_\_\_

Shipping Cost \$ \_\_\_\_\_ Total Reimbursement \$ \_\_\_\_\_

Please make a copy of the form for your records and send one along with the the returned product.

Use the enclosed label and return to:

CSL Behring, L.L.C.

*Attention: Monoclote-P 1000 Unit Recall*

1201 N. Kinzie

Bradley, IL 60915

*Thank you for your help and consideration.*

# CSL Behring

August 18, 2008

## URGENT: BIOLOGIC RECALL

Subject: Monoclate-P®, 1000 Unit Vials  
Antihemophilic Factor, Human  
Lot Numbers J91504, J91604, J91705 and J91806

Dear Colleague:

CSL Behring L.L.C. has decided to initiate a voluntary recall of Monoclate-P®, 1000 Unit, lots J91504, J91604, J91705 and J91806, with expiration dates of April 25, April 30, May 2, and June 9, 2010, respectively. This action is being taken with the knowledge of the United States Food and Drug Administration.

These lots are being voluntarily recalled as a precautionary measure. These lots do not meet the potency specification when stored for three months at 5° C. As of this date, no technical complaints or adverse events have been reported against any of these lots. CSL Behring is requesting that the use of these lots be immediately discontinued and the product be returned to the company.

Vials from all four batches were distributed beginning on August 4, 2008. Our records indicate that you have been shipped vials from one of these lots of Monoclate-P®:

NDC No.	Lot	Potency	Expiration Date
0053-7656-04	J91504	925 IU	April 25, 2010
0053-7656-04	J91604	960 IU	April 30, 2010
0053-7656-04	J91705	975 IU	May 02, 2010
0053-7656-04	J91806	960 IU	June 09, 2010

This voluntary recall is to the pharmacy level.

Please examine your inventory of Monoclate-P®, 1000 Unit vials for lots J91504, J91604, J91705 and J91806. Please immediately discontinue distribution and use of any on-hand stock from these lots. Return that stock to CSL Behring.

Healthcare providers and homecare companies should contact their customers and advise them to return these lots of Monoclate-P® to CSL Behring.

Regardless of whether or not you have any inventory or product from these lots, please immediately take the following actions:

- 1) If you have any inventory of Monoclate-P®, 1000 Unit lots J91504, J91604, J91705 and J91806, please complete the Returned Goods Form. Return the completed Returned Goods Form and all vials in inventory of Monoclate-P®, 1000 Unit lots J91504, J91604, J91705 and J91806, to the following address:

CSL Behring L.L.C.  
Attention: Monoclate-P®, 1000 Unit Recall  
1201 N. Kinzie  
Bradley, IL 60915

- 2) If you have further distributed these lots, you should notify your customers to the pharmacy level.

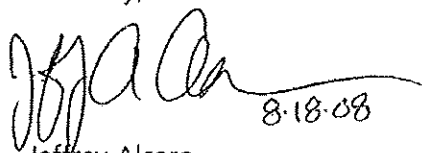
Customers who have purchased product directly from CSL Behring will be credited for every returned vial of inventory of Monoclate-P®, 1000 Unit lots J91504, J91604, J91705 and J91806, and CSL Behring shall bear the shipping costs. Customers who purchased product through a healthcare provider or a homecare company will be credited through their healthcare provider or homecare company, respectively.

PLEASE NOTE THAT RETURNS ARE LIMITED TO INVENTORY OF MONOCLATE-P®, 1000 UNIT FOR LOTS J91504, J91604, J91705 and J91806 ONLY. THERE WILL BE NO CREDIT GIVEN FOR RETURNS OF ANY OTHER LOTS OF MONOCLATE-P® THAT YOU HAVE IN INVENTORY OR RETURNED BY YOUR CUSTOMERS.

If you have any questions concerning product returns, please call Customer Support at 1-800-683-1288. For Medical Information questions, please call 1-800-504-5434.

Thank you for your cooperation in this matter.

Sincerely,



8.18.08

Jeffrey Alcorn  
Senior Director, Quality

CC: Kathleen Haas (CBER Recall Coordinator)  
FDA Recall File – Kankakee