

To: DC Managers
From: Cynthia Gaw
Date: November 3, 2010
RC: 10-196A

URGENT!!! DRUG RECALL!!! URGENT!!!

UPDATE: MCKESSON CUSTOMER INSTRUCTIONS

FDA/SUPPLIER CLASS OF RECALL: Not Yet Classified
LEVEL OF NOTIFICATION: McKesson Customer
SUPPLIER: Medefil, Inc. # 28595

Description	Lot #	Exp Date	NDC	UPC	Econo #
SYR HEP 100UN 3ML FIL 12ML 60	H109298	08/2011	64253033333	36425333333	1303874
	H110152	01/2012			
SYR HEP 100UN 5ML FILL 12ML 60	H109291	08/2011	64253033335	36425333335	1304203
	H109293	08/2011			
	H109295	08/2011			
	H109297	08/2011			
	H109299	08/2011			
	H109300	08/2011			
SYR HEP 10UN 1ML FILL 6ML 60	H10228	04/2012	64253022221	36425322221	1946656
SYR HEP 10UN 3ML FILL 6ML 60	H10262	05/2012	64253022223	36425322223	1632298
SYR HEP 10UN 5ML FILL 12ML 60	H10190	03/2012	64253022235	36425322235	1304120
	H10229	04/2012			
	H10278	06/2012			
SYR HEP 1UN 2ML FILL 6ML 60	H210209	04/2012	64253044422	36425344422	1304070
	H210238	05/2012			
	H210265	05/2012			
SYR HEP 1UN 5ML FILL 6ML 60	H210210	04/2012	64253044425	36425344425	1631845
	H210241	05/2012			

Medefil, Inc. is voluntarily recalling the above lots because Scientific Protein Laboratories LLC additional testing of retained crude heparin samples used by SPL to manufacture this single API lot indicated a trace amount of oversulfated chondroitin sulfate (OSCS) contaminant. Medefil, Inc. tested the affected API lots from Scientific Protein Laboratories LLC during routine incoming inspection and found no evidence or presence of OSCS when tested using then current USP Monograph methods. This recall is to the McKesson Customer level.

Please check your inventory for the above lots. Complete and return the business reply card via fax to 630-681-9100 even if you do not have the affected lots. If you have the affected lots, stop distributing immediately. Contact Medefil Customer Service at 630-682-4600 for return instructions and RGA number. Return product to the address below. Credit will be issued for products received under the RGA.

Medefil, Inc.
250 Windy Point Drive
Glendale Heights, IL 60139

McKesson customers are to check their inventory and return McKesson Distribution Centers.

Contact Medefil Customer Service at 630-682-4600 if you have additional questions on this recall.

This recall is being conducted with the knowledge of the FDA.

Information contained in this document was provided by Medefil, Inc.

FOR McKESSON USE ONLY:

- Please follow Recall Guidelines as outlined in the Reclamation SOP for a CLASS II RECALL.
- PROCESS TO THE RETAIL LEVEL.

Medefil Urgent Recall Response Form

Please complete, sign and fax this response to Ms. Laura Warren at fax number (630) 681-9100 to confirm receipt of Medefil Recall Letter and your intent to arrange shipment to Medefil, Inc. 250 Windy Point Drive, Glendale Heights, Illinois 60139 for the recalled lots.

Material on Hand:

Lot Number	Quantity on Hand
H109291	
H109293	
H109295	
H109297	
H109298	
H109299	
H109300	
H110152	
H10190	
H210209	
H210210	
H10228	
H10229	
H210238	
H210241	
H10262	
H210265	
H10278	

Note:

1. Return Good Authorization (RGA) must be obtained from Medefil prior to shipping any products back to Medefil.
2. Credit will only be issued for product received under the RGA and only for products possessing the above lot numbers.

Distributor Name: _____

Signature & Title (I have knowledge of my firm's product inventory and disposition)

Telephone Number

Date