



January 28, 2011

URGENT: DRUG RECALL
RETAVASE® (reteplase, recombinant)

Dear Customer:

Alcohol Prep Pads included in four (4) lots of RETAVASE® (reteplase, recombinant) FULL Kits may have been contaminated. Each full kit (see attached illustration) contains two (2) 10 Unit vials of sterile lyophilized RETAVASE powder for reconstitution. As a precaution, EKR Therapeutics, Inc. is initiating a voluntary product recall of all FULL kits of RETAVASE with the following lot numbers, which were first distributed in November, 2008 and which expire in April 2011:

<u>Lot Number</u>	<u>NDC Number</u>
522203F-04	67286-040-01
522203F-05	67286-040-01
522253F-07	67286-040-01
522253F-09	24477-041-02

Note: The Lot Number is located on the end of the Full Kit box and each kit contains *two* Alcohol Prep Pads (see attached illustration). **THIS RECALL IS ONLY FOR THE ABOVE MENTIONED LOTS AND ONLY FOR FULL KITS.**

Please check your inventory carefully, discontinue distribution and use of all RETAVASE full kits with the above mentioned lot numbers and return any opened and unopened kits to the following address:

Cardinal Health Specialty Pharmaceutical Services, 15 Ingram Blvd., Dock 43, LaVergne, TN 37086

You will be issued a credit for the full kits returned, as well as for any handling and shipping fees..

If you have any questions about returns, you can contact EKR Therapeutics at 1-877-207-5802.

We request that wholesalers contact any customers that may have purchased lots 522203F-04, 522203F-05, 522253F-07 and/or 522253F-09 and instruct them to return any unused product (both opened and unopened) so that it may also be returned to Cardinal Health Specialty Pharmaceutical Services, as indicated above.

Enclosed is a postage-paid form on which to record your current inventory of recalled material and the number of customers directly contacted. Please complete and mail this form (even if you have no inventory to return), because it will be used for accountability purposes. **Do not enclose this form with the product you are returning.**

This recall is being made with the knowledge of the Food and Drug Administration. We appreciate your assistance in this matter.

Sincerely,

EKR THERAPEUTICS, INC.