



**SECOND MAILING
JUNE 16, 2010**

**Urgent
Product Recall**



Rec'd SSD

JUN 18 2010

May 24, 2010

**Re: HYLENEX – Recombinant (Hyaluronidase Human Injection)
Physician Samples, Lot: 909777**

Dear Healthcare Professional:

Our records indicate that you may have received physician samples of the lot of HYLENEX Recombinant (Hyaluronidase Human Injection) listed below.

Lot Number	NDC Numbers	Expiration Date
909777	60977-319-44 60977-319-02 60977-319-99	August 2010

Halozyne Therapeutics, Inc. (Halozyne) is performing a voluntary recall of the above lot of HYLENEX recombinant (Hyaluronidase Human Injection). Baxter Healthcare Corporation (Baxter) is executing this recall on behalf of Halozyne.

As a part of routine stability inspections, a limited number of vials were observed to contain small, flake-like glass particles. With patient safety as our top priority, a voluntary recall is being initiated for all distributed lots of HYLENEX. This action is being taken as a precautionary measure. To date, no medical events or customer complaints associated with this issue have been reported.

Please take the following actions immediately regarding the affected product.

1. Examine your inventory to determine if you have any product. If so, remove the affected product from inventory and contact the Baxter Pharmaceuticals and Technologies Customer Service at 1-800-667-0959 to arrange for the product return.
2. Please complete the attached reply form confirming your receipt of this letter and fax it to Baxter at the number provided on the form. We are required by the FDA to obtain responses from our customers on notifications of this nature. Returning the form promptly will prevent you from receiving a repeat notice.

We appreciate your immediate attention and cooperation. If you have any technical or clinical questions, please contact the Medical Information Services at Baxter at 1- 800-262-3784.

If you have distributed HYLENEX recombinant (hyaluronidase human injection) to other services or facilities, please forward this communication to the appropriate parties.

We apologize for any inconvenience this may cause you and your staff. If you have any additional questions, please call the Center for One Baxter at 1-800-422-9837.

The FDA has been notified of this communication.

Sincerely,



Don Kennard
Vice President Regulatory Affairs
and Quality Assurance
Halozyme Therapeutics



Raymond P. Godlewski
Vice President Quality
Baxter Pharmaceuticals and
Technologies

**CUSTOMER REPLY FORM
URGENT PRODUCT RECALL
May 24, 2010**

HYLENEX – Recombinant (Hyaluronidase Human Injection)

Lot Number	NDC Numbers
909777	60977-319-44, 60977-319-02, 60977-319-99

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

1 (847) 270 5457

Facility Name and Address:	<p align="center">34230050 2010-027-MD 2 Healthcare Professional TEXAS TECH UNIV HLTH & 3601 4TH ST LUBBOCK TX 79430</p>
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Please check the applicable boxes below:

- We have inventory of the affected lot numbers. We have, or will, contact Baxter to arrange for the return of these units.
- We have no remaining inventory of the affected units.

PLEASE ENSURE THE BELOW IS COMPLETED. BAXTER CANNOT PROCESS UNSIGNED FORMS. RESPONDING TO THIS REQUEST WILL PREVENT THE RECEIPT OF UNNECESSARY REPEAT NOTIFICATIONS CONCERNING THIS ISSUE.

Your signature below indicates understanding the contents of the attached letter; performing the actions as outlined in the letter, as needed; and dissemination of this information to staff and other services or facilities, as applicable.

Signature/Date:

Please sign and date in the required field: _____

Reply Confirmation Completed By: <i>(Please print name)</i>	
Title: <i>(Please print)</i>	
Telephone Number <i>(including Area Code):</i>	