Baxter Healthcare Corporation 847.546.6311
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Baxter

# Urgent Product Recall

January 17, 2008

Re: Heparin Sodium Injection 1000 units/mL 10mL Vial
Lot #'s 107054 and 117085
Heparin Sodium Injection 1000 units/mL 30mL Vial
Lot #'s 047056, 097081, 107024, 107064, 107066, 107074, and 107111

Dear Customer/Wholesaler/Distributor:

Baxter Healthcare is performing a **voluntary recall** of the above lots of Heparin as a precaution due to an increase in reports of adverse patient reactions including abdominal pain, abdominal pain (upper), decreased blood pressure, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, hypotension, lacrimation increased, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, paresthesia (oral), pharyngeal edema, restlessness, vomiting/retching, stomach discomfort, tachycardia, thirst, trismus, and unresponsiveness to stimuli. We have received no reports involving fatality. Our records indicate that you have received the above affected Heparin Sodium 1000 unit/mL for injection manufactured by Baxter.

Baxter is in the process of an in-depth investigation to determine the root cause of the reported reactions.

| NDC # | Lot # | Description | Expiration Date |
|---|---|---|---|
| 0641244045 | 107054 | Heparin 1000units/mL 10mL vial | 10/2009 |
| 0641244045 | 117085 | Heparin 1000units/mL 10mL vial | 11/2009 |
| 0641245045 | 047056 | Heparin 1000units/mL 30mL vial | 10/2008 |
| 0641245045 | 097081 | Heparin 1000units/mL 30mL vial | 09/2009 |
| 0641245045 | 107024 | Heparin 1000units/mL 30mL vial | 10/2009 |
| 0641245045 | 107064 | Heparin 1000units/mL 30mL vial | 10/2009 |
| 0641245045 | 107066 | Heparin 1000units/mL 30mL vial | 10/2009 |
| 0641245045 | 107074 | Heparin 1000units/mL 30mL vial | 10/2009 |
| 0641245045 | 107111 | Heparin 1000units/mL 30mL vial | 10/2009 |

**Please immediately discontinue use and segregate the above affected lot numbers.**


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1. Examine your inventory to determine if you have any affected product. If so, remove the affected product from your inventory and contact Baxter Healthcare Center for Service at 1-888-229-0001 to arrange for return and credit.

2. If you have distributed the affected lot numbers of Heparin to other services or facilities, or if you are a dealer, wholesaler or distributor/reseller of any of the affected products, please forward this communication as appropriate. Any distributed product is to be returned according to this notification.

Please complete the attached reply form confirming your receipt of this letter and fax it to Baxter at the number provided on the form. Baxter is 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 apologize for any inconvenience this may cause you or your staff. If you have any technical or clinical questions, please contact Baxter Healthcare Corporation Product Information Center at 1-800-933-0303.

The FDA has been notified of this communication.

Sincerely,

David Rohrbach

David Rohrbach
Vice President, Quality
Baxter Pharmaceuticals and Technologies
Baxter Healthcare Corporation



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Heparin Sodium Injection 1000 units/mL 10mL Vial
Heparin Sodium Injection 1000 units/mL 30mL Vial

CUSTOMER REPLY FORM
URGENT PRODUCT RECALL
January 17, 2008

| NDC # | Lot # | Description |
|---|---|---|
| 0641244045 | 107054, 117085 | Heparin 1000units/mL 10mL vial |
| 0641245045 | 047056, 097081, 107024, 107064, 107066, 107074, 107111 | Heparin 1000units/mL 30mL vial |

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: | |
|---|---|

☐ We have inventory of the affected lot numbers and have contacted Baxter to return affected product.

☐ We have no remaining inventory of the affected units.

We understand the contents of the letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

Signature/Date:
REQUIRED FIELD _____

| Reply Confirmation Completed By: *(Please Print Name)* | |
|---|---|
| Title: *(Please Print)* | |
| Telephone Number (Including Area Code): | |



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