SAGENT

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Road, Suite 700
Schaumburg, IL 60195
(847) 908-1690 Main
(847) 908-1691 Fax
www.SagentPharma.com

CUSTOMER NOTIFICATION/ RECALL COMMUNICATION
URGENT: AMIODARONE HCl INJECTION, 150mg/3mL RECALL

March 9, 2011

Dear Valued Customer:

This letter is to inform you that Sagent Pharmaceuticals, Inc. is voluntarily recalling the following product:

Product	Lot Number(s)	NDC Number	Distribution Dates
Amiodarone HCl Injection, 150mg/3mL	ER001, ER002, ER003, ER004, ER005, ER006, ER007, ER008, ER009, ER010	25021-302-73	April 8, 2010 – March 8, 2011

This recall is being made with the knowledge of the Food and Drug Administration and has been initiated due to reports of incompatibility of certain needleless I.V. sets with Luer-Activating Devices with Sagent's Amiodarone Prefilled Syringes, resulting in adverse events.

To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to recall.
2. Immediately discontinue use and distribution of the attached listed lots. A credit memo will be issued covering the quantity of your product returned.
3. Return product to:

   DDN Logistics
   ATTN: Returns Department
   4580 S. Mendenhall
   Memphis, TN 38141

   NOTE: A call tag, a pre-printed, pre-paid return label will be provided to you for product return; return shipment is free of charge. For the call tag, contact DDN Customer Service at 1-866-625-1618, option 1. You will be asked for the product weight which is required for generation of the call tag.

4. If you may have further distributed this product, please identify those customers and notify them at once of this product recall. Your notification to your customers should include a copy of this recall notification letter.
5. Please complete and return the enclosed "Customer Recall Return Response Form" as soon as possible and fax the form to us at 1-847-908-1827.

This recall should be carried out to the user level. Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Program by fax at 1-800-fda-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787 or on the MedWatch website at www.fda.gov/safety/medwatch/default.htm.

Your assistance is appreciated. I apologize for any inconvenience this may cause you.

If you have any questions, please do not hesitate to call our Customer Service at **1-866-625-1618** which was specifically set-up to address any concerns that you may have.

Sincerely,

Sheila Moran
Vice President Quality Assurance & Facility Compliance
Sagent Pharmaceuticals, Inc.
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CUSTOMER RECALL RETURN RESPONSE FORM

PLEASE FAX COMPLETED RESPONSE FORM TO 1-847-908-1827 (ATTN: QA Dept)

Product	Lot Number(s)	NDC Number
Amiodarone HCl Injection, 150mg/3mL	ER001, ER002, ER003, ER004, ER005, ER006, ER007, ER008, ER009, ER010	25021-302-73

Please check ALL appropriate boxes.

☐ I have read and understand the sub-recall instructions provided in the Customer Notification/Recall Communication letter dated March 9, 2011.

☐ I have checked my stock and have quarantined inventory consisting of _____ units (Pre-Filled Syringes).

Indicate disposition of recalled product:

Disposition	Quantity	Date	Method
☐ returned			
☐ quarantined			

☐ I have identified and notified my customers that were shipped or may have been shipped this product and have communicated that we are conducting a sub-recall to our direct account customers.

Date of communication:_____

Method of communication:_____

Have there been any Adverse Events associated with recalled product? ☐ Yes ☐ NO

If yes, please explain: _____

Please check the appropriate box(es) to describe your business

☐ wholesaler/distributor ☐ retailer ☐ pharmacy – retail ☐ hospital pharmacies

☐ hospital/medical facility ☐medical laboratory ☐Other:_____

Please Complete Contact Information for Person Completing Response:	
Name:	
Title:	
Tel Number:	
Facility:	
Address:	
City, State, Zip:	