



SAGENT®

Sagent Pharmaceuticals, Inc.

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**CUSTOMER NOTIFICATION/ RECALL COMMUNICATION
URGENT: OXACILLIN for INJECTION, USP, 10g RECALL**

August 17, 2016

Dear Valued Customer:

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

Product	Lot Number	NDC Number	Distribution Dates
Oxacillin for Injection, USP, 10g	OXT512 - Exp date: March 2017	25021-163-99	June 2016 – July 2016

This recall is being made with the knowledge of the Food and Drug Administration and has been initiated due to the receipt of a product complaint for a single vial containing small, dark particulate matter found within the solution after reconstitution. The particulate matter has been identified as iron oxide.

In the event that metal particulate in an injectable product is administered to a patient, it may result in local swelling, irritation of blood vessels or tissue, or blockage of blood vessels. Blockage of blood vessels can lead to serious events, which may be life-threatening, such as stroke, heart attack, respiratory failure, kidney failure, or liver failure. To date, Sagent is not aware of any known adverse patient events resulting from the use of the subject product lot.

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 identified lot number. A credit memo will be issued covering the quantity of your product returned.
3. Return product to:
DLSS (DOHMEN Life Science Services)
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 DLSS 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. Wholesalers: No call necessary, just send debit memo via email or fax: orders@sagentpharma.com or fax to 1-866-821-5358.

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 1-901-368-6903. The completed form may also be emailed to DDNRegulatory@ddnnet.com.

This recall should be carried out to the **user level**.

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**, M-F 8am – 7pm CST, which was specifically set-up to address any concerns that you may have.

Sincerely,

Bob Quesinberry
Vice President, Global Quality and Facility Compliance
Sagent Pharmaceuticals, Inc.
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