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: FLUCONAZOLE INJECTION, USP (IN 0.9% SODIUM CHLORIDE), 200mg per 100mL RECALL

March 1, 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
Fluconazole Injection, USP (in 0.9% Sodium Chloride), 200mg per 100mL	40608 - Exp date May 2017	25021-113-82	November 2014 – December 2014

This recall is being made with the knowledge of the Food and Drug Administration and has been initiated due to the discovery of an out of specification impurity result detected during routine quality testing of stability samples at the 18-month interval. This impurity has been identified as Metronidazole.

An elevated impurity has the potential to decrease effectiveness of the product in patients. Patients on the product and on concomitant medication of Metronidazole may receive an increased dose of Metronidazole. Sagent is not aware of any adverse patient events resulting from the use of the product identified in the table above.

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

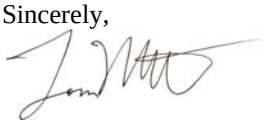
   NOTE: A call tag, a pre-printed, pre-paid return label will be provided to you for product return; return shipment is free of charge. For the call tag, contact DLSS Customer Service at 1-866-625-1618, option 1. You will be asked for the product weight which is required for generation of the call tag.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



Tom Moutvic
Vice President Regulatory Affairs/Interim Vice President Quality Assurance & Facility Compliance
Sagent Pharmaceuticals, Inc.
1901 N. Roselle Road, Suite 700, Schaumburg, IL 60195