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From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, November 27, 2017 1:50 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: FDA Medwatch - Riomet (Metformin Hydrochloride Oral Solution) Recall

Riomet (Metformin Hydrochloride Oral Solution): Recall - Microbial Contamination

AUDIENCE: Pharmacy, Patient

ISSUE: Sun Pharmaceutical Industries is recalling two lots of Riomet (Metformin Hydrochloride Oral Solution), which were found to be contaminated with Scopulariopsis brevicaulis. Use of the affected Riomet potentially could result in a risk of infection, especially in the immunocompromised patient. The most plausible portal of entry of Scopulariopsis brevicaulis is the respiratory tract, where it may cause pneumonia, sinusitis and disseminated infections.

The affected Riomet includes product with NDC Code 10631-206-01 Lot A160031A, Exp.: 01/2018, and NDC 10631-206-02 Lot: A160031B, Exp.: 01/2018.

BACKGROUND: The contamination was discovered during sample preparation for the Antimicrobial Preservative Effectiveness Testing (AMPET) being performed as part of the 12 month stability study interval.

Riomet (Metformin Hydrochloride Oral Solution) is indicated to treat type 2 diabetes mellitus in adult and children age 10 and above. Riomet is packaged in 118 mL (4 fl. oz.) and 473 mL (16 fl. oz.) bottles.

RECOMMENDATION: On April 18, 2017, SPII notified its wholesale customers through its 3rd party Recall Coordinator (Inmar Inc.) via FedEx standard overnight shipping and has arranged for the return via prepaid FedEx Ground shipping of all recalled products. Consumers that have Riomet (Metformin Hydrochloride Oral Solution) which has been recalled should stop using and return it to place of purchase, discard and/or contact their doctor.

Consumers with questions regarding this recall can contact SPII by calling 1-800-406-7984, Monday through Friday between 8:00 am to 5:00 pm EST or emailing drug.safetyUSA@sunpharma.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch Safety Alert, including a link to the press release, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm586510.htm

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.