



Company Recalls Compounded Medications for Safety Concerns

Background:

The US Food and Drug Administration (FDA) announced that US Compounding, Inc. was voluntarily recalling all lots of sterile products compounded and packaged by US Compounding, Inc. and that remain within expiry due to FDA concern over a lack of sterility assurance.¹ The products were distributed nationwide to patients, providers, hospitals, or clinics between March 14th, 2015 and September 9th, 2015.

Recommendation:

All patients and providers that received sterile compounded products from US Compounding, Inc. between March 14, 2015 and September 9, 2015, and that remain within expiry, are advised to take the following actions¹:

- Discontinue use of the products
- Quarantine any unused product until further instructions are received on how to return the product
- Contact US Compounding, Inc. at 800.718.3588 x254 or 501.327.1222 x254, or e-mail at questions@uscompounding.com to discuss the return of any unused products

Patients are advised to contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Providers who have dispensed any of these products to a patient(s) for use outside of the provider's office should contact the patient(s) to whom product was dispensed and advise the patient(s) of this recall.

Impact to Our Customers:

No claimants are identified within Healthcare Solutions' books of business who would be impacted by this recall on the basis of an examination of fills for the labeler code alert of 62295-****-** for US Compounding, Inc. during March 14th, 2015 to September 9th, 2015². Healthcare Solutions supports all efforts to ensure safe and appropriate medication use, including those related to the use of compounded medications. Healthcare Solutions' clinical programs can help claim administrators identify, evaluate and address potential compound use in their injured workers and intervene when appropriate.

For questions regarding this eAlert or to learn more about our Clinical Rx Services please contact your dedicated Account Executive.

Sources:

1. U.S. Food and Drug Administration. (2015). Sterile Compounded Products by US Compounding, Inc: Recall - Lack of Sterility Assurance. [Press release]. Available at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm464086.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
2. Healthcare Solutions internal dataset, March 14, 2015 through September 9, 2015.

Healthcare Solutions' clinical pharmacist team actively monitors and communicates timely news and announcements from the FDA affecting prescription drug management. We are committed to notifying you of important information as well as offering consultation on how these updates may impact your claimants and pharmacy management program.

Disclaimer

This alert is offered as a general summary of information retrieved from a variety of sources, including scientific literature and clinical experience. We seek to provide useful, current reference material, but do not claim to provide a comprehensive review and cannot guarantee the accuracy of information presented. Opinions are those of individual authors, and do not necessarily represent the recommendation or endorsement of Healthcare Solutions. This communication does not constitute medical advice.

