



West Pharmaceutical Services, Inc.
530 Herman O. West Drive
Exton, PA 19341
www.westpharma.com

May 29, 2020

Dear Valued Customer,

We would like to inform you that on May 28, 2020, West Pharmaceutical Services, Inc. (West) submitted a Traditional 510(k) pre-market notification to the United States Food and Drug Administration (FDA) for review of the new Vial2Bag Advanced™ 20mm Admixture Device.

Since January 2019, West has been working with your organization to complete a voluntary recall of its Vial2Bag® Direct Connect (DC) fluid transfer device. Once notified of reports of variable or unpredictable dosing of the drug oxytocin, West recalled this product out of an abundance of caution. No adverse events were reported in relation to any other drug product.

During this time, West focused on developing a next generation Vial2Bag Advanced admixture device, while working closely with the FDA to close out the activities related to the voluntary recall of the former Vial2Bag DC device.

Your patience has been greatly appreciated as we have worked to complete the necessary activities in development of a new needle-free device, which enables the preparation of IV medication outside of the pharmacy for point of care administration. This new design addresses many of the issues relating to resource constraints, needle safety, drug loss and delay in treatment of critical care patients, which healthcare providers may experience in the preparation of drugs for IV infusion administration.

We understand that a point of care solution is needed now more than ever in the current healthcare climate. We are currently working through the regulatory process and look forward to introducing our new device once we receive clearance from the FDA.

Sincerely,

A handwritten signature in black ink that reads "Cindy Reiss-Clark". The signature is written in a cursive, flowing style.

Cindy Reiss-Clark
SVP, Market Units and Commercial Solutions
West Pharmaceutical Services, Inc

Vial2Bag® is a registered trademark and Vial2Bag Advanced™ is a trademark of West Pharma. Services IL, Ltd., a subsidiary of West Pharmaceutical Services, Inc.