

12, April 2021

Dear Healthcare Professional,

This letter serves to address the possibility of unreadable bar codes on Single-Dose Vials due to wrinkling of the labels.

A thorough investigation has been completed, which included review of the manufacturing process records, as well as inspection of retained samples of the lots involved. The investigation determined that the wrinkling of the labels was isolated to vials produced on one line at one site during June and July 2020. Possible products impacted are 1g Ceftriaxone, 1g Cefazolin and 1g Cefoxitin. The wrinkling of the vial label occurred randomly across those affected lots.

We would like to emphasize that WG Critical Care takes this event very seriously and has been working with the manufacturing site to implement Corrective and Preventive Action (CAPA):

- A Field Alert Report was filed with the US FDA as required.
- The involved equipment has been maintained to eliminate or abate any risk of wrinkles over the label bar codes.
- Additional in-line quality control checks have been implemented according to Acceptable Quality Limits (AQL) protocols, which include physical inspection of the labels and periodic checks for legibility of the bar codes. This will effectively enable the manufacturing site to be aware of the issue should it occur in the future.

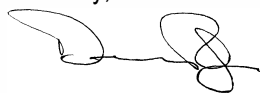
The bar code defect has no impact on the safety and quality of the product and there is no change on the drug product's identity, strength, purity, stability, and efficacy. With the implementation of these corrective actions, the manufacturing site is confident that the issue has been satisfactorily addressed.

If you have any additional questions, please feel free to contact WG Critical Care.

WG Critical Care Customer Service  
1-888-493-0861  
WGCCcustomerservice@eversana.com

Medical Information  
1-866-562-4708  
productcomplaint@propharmagroup.com

Sincerely,



Deena Reyes  
Chief Commercial Officer  
WG Critical Care, LLC