

Provider Newsflash April 21, 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has posted notice of a voluntary recall by B. Braun Medical, Inc. of one (1) lot of 2g Ceftazidime for Injection USP (2g) and Dextrose for Injection USP (50 ml) in Duplex[®] Container to the hospital/user level.. During stability testing of Batch H8J812, test results were found to exceed the specification limits for High Molecular Weight Polymers (HMWP) at the nineteen (19) month [82 week] stability interval.

What do I need to do?

- Please review the following recall notice:
- <u>https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/b-braun-</u> <u>medical-inc-issues-voluntary-nationwide-recall-one-1-lot-ceftazidime-injection-usp-</u> <u>and?utm_campaign=FDA%20MedWatch%20Ceftazidime%20Injection%20by%20B.%2</u> <u>OBraun%3A%20Recall&utm_medium=email&utm_source=Eloqua</u>
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by:
 - Faxing information- To: 919-792-6718 Attn: Quality Department

Thank you for your prompt attention and cooperation in this matter.