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July 31, 2015

Dear Sir / Madam,

As a valued customer of BD, we want to make you aware of information pertaining to our BD 3mL and BD 5mL plastic sterile hypodermic syringes. Recently, a few hospital pharmacies and outsourced compounding facilities have informed us of their use of these syringes for storage of compounded pharmaceuticals. Those customers have also informed us of reduced potency of certain medications when stored in these syringes. The degradation of drug potency occurs when the compounded pharmaceuticals are stored for periods of time exceeding 24 hours. The results are based on testing that these hospital pharmacies and outsourced compounding facilities are required to perform as compounders of pharmaceutical products.

Please note, decreased potency is not observed when syringes are filled and used promptly, as per the FDA clearance.

While under law hospital pharmacies and outsourced compounding facilities on their own are free to decide to utilize our syringes for these purposes, BD plastic sterile hypodermic syringes are not FDA-cleared for storage of compounded pharmaceuticals.

Periodically, we modify some components of our syringes for various commercial and/or technical reasons. Before releasing the modified syringe, we conduct testing to ensure that the modifications do not impact the safety and performance of the FDA-cleared use of the syringe, i.e. general purpose fluid aspiration/injection. However, we do not test non-FDA-cleared uses of the device such as storage of compounded pharmaceuticals. Nor do we publish anything to alert users to the changes we periodically make in the products.

Nonetheless, based on this feedback from these hospital pharmacies and outsourced compounding facilities, we are currently investigating the root cause and potential contributing factors to the reported decreased potency occurring over an extended storage time.

If you have any questions, please feel free to contact your local BD Sales Consultant and they will be able to connect you with our Medical Affairs professionals to discuss further.

Sincerely,

A handwritten signature in black ink, appearing to read 'Brad Noe'.

Brad Noe
Global Manager, Technical & Clinical Support
BD Medication & Preparation Solutions