



March 21st, 2024

Dear Valued Medline Customer,

On March 19th, 2024 the U.S. Food and Drug Administration (FDA) issued an update to their November 2023 press release relating to plastic syringes manufactured in China.

FDA noted that it had issued a Warning Letter to Medline and two other firms, Jiangsu Shenli Medical Production Co. Ltd. and Sol-Millennium Medical, Inc. regarding certain syringes that FDA alleges require separate 510(k) clearances. FDA's update further recommends that consumers, health care providers, and facilities immediately transition away from using plastic syringes manufactured by Jiangsu Caina Medical Co. Ltd. and unauthorized plastic syringes manufactured by Jiangsu Shenli Medical Product Co Ltd. Both of these manufacturers are in Medline's supplier community.

At this time Medline is actively working with FDA to determine our path going forward. We want to be sure that the Agency is aligned with our next steps and that we are managing this in a way to minimize any supply disruption to our customers.

The FDA Safety Communication relating to these syringes states, "Continue to use them as needed only until you are able to transition to alternatives and closely monitor for leaks, breakage, and other issues, and report any problems to the FDA." Please note that Medline's internal data indicates that our syringes have a defect-free rate of 99.9998% (complaint rate equivalent to <0.0001%) and we have no indication of any negative trend related to performance of these syringes.

Medline will continue to work to obtain replacement product or acceptable alternatives and we will communicate any changes or additional information as quickly as possible.

Regards,

Lara N. Simmons

Chief Quality Officer