FDA Provides Update on Plastic Syringes Made in China, Issues Warning Letters Related to Violative Products

FOR IMMEDIATE RELEASE

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The following is attributed to Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health (CDRH)

Today, the FDA is providing an update (/medical-devices/safety-communications/update-evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication) on our ongoing evaluation of quality and performance issues related to plastic syringes made in China, and announcing additional recommendations and actions the FDA is taking.

On November 30, 2023, the FDA issued a safety communication (https://public4.pagefreezer.com/browse/FDA/13-03-2024T15:34/https://www.fda.gov/medical-devices/safety-communications/evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) related to the agency's evaluation of potential device failures with certain plastic syringes made in China. The FDA previously received information about concerns with the performance and safety of these syringes, including their ability to deliver the correct dose of medication when used alone or with other medical devices such as infusion pumps.

The FDA has continued its extensive efforts to evaluate problems with plastic syringes made in China, including facility inspections for Medline Industries, LP and Sol-Millennium Medical, Inc., examining and detaining products at the border, laboratory testing of syringes, and working with applicable manufacturers to ensure adequate corrective actions are taken. Our ongoing evaluation has confirmed that issues with the quality of plastic syringes made in China and their distribution in the U.S. are more widespread than originally known.

As such, on March 18, 2024, the FDA issued a warning letter to Jiangsu Shenli Medical Production Co. Ltd, a China-based manufacturer of plastic syringes, and warning letters to Medline Industries, LP and Sol-Millennium Medical, Inc., two firms marketing and distributing plastic syringes made in China within the U.S. All three warning letters describe violations related to the sale and distribution of unauthorized plastic syringes made in China that have not been cleared or approved by the FDA for use in the U.S. The warning letters for Medline

Industries, LP and Sol-Millennium Medical, Inc. also concern violations related to quality system regulations for syringe products. The FDA expects these entities to fully address the violations described in the warning letters.

In addition, the FDA is actively evaluating quality issues and performance testing failures with plastic syringes made by Jiangsu Caina Medical Co. Ltd, a China-based manufacturer cited in the warning letter issued to Medline Industries, LP. The FDA is aware of performance testing that showed unexpected and unexplained failures with several Jiangsu Caina plastic syringes. The FDA evaluation is ongoing and we will take additional steps as appropriate.

At this time, the FDA is providing additional recommendations to our November 2023 safety communication. Until further notice and because of potential quality and performance issues, the agency recommends that U.S. suppliers, consumers, and health care organizations immediately transition away from using plastic syringes manufactured by Jiangsu Caina Medical Co. Ltd and unauthorized plastic syringes manufactured by Jiangsu Shenli Medical Production Co. Ltd (which includes all models other than the 5 mL luer lock syringe), unless absolutely necessary until the transition is complete. As this is an ongoing evaluation, for all other plastic syringes made in China, the agency's recommendations remain unchanged from our November 2023 safety communication. 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. This issue does not include glass syringes, pre-filled syringes, or syringes used for oral or topical purposes. To determine if your syringes were made in China, confirm the manufacturing location by reviewing the labeling, outer packaging, or contacting the supplier or group purchasing organization.

The FDA believes that the supply and manufacturing capacity of plastic syringes made in countries other than China, including domestic manufacturing, is adequate to support current health care demand. Therefore, the agency does not anticipate that a shift in the supply chain is likely to lead to a shortage of these products.

The FDA will continue to work with stakeholders, including other federal agencies, medical device manufacturers, and health care organizations to ensure the safety of syringes being used in the U.S. In addition, the FDA will continue our efforts to evaluate problems with syringes made in China and keep the public informed as additional information becomes available.

Additional Resources:

- UPDATE: Evaluating Plastic Syringes Made in China for Potential Device Failures: FDA Safety Communication (/medical-devices/safety-communications/update-evaluating-

plastic-syringes-made-china-potential-device-failures-fda-safety-communication) (March 2024)

- Warning Letters:
  - Jiangsu Shenli Medical (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jiangsu-shenli-medical-production-co-ltd-677753-03182024)
  - Sol-Millennium Medical (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sol-millennium-medical-inc-677524-03182024)
  - Medline Industries (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/medline-industries-lp-677545-03182024)