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News We're Watching: Widespread Plastic Syringe Issues, Call For TAP Pilot Comments, AdvaMed/FDA Conference, Warning Letter Roundups

by Hannah Daniel

This week, the US FDA issued an update on its safety warning for plastic syringes made in China; AdvaMed announced a medical device and diagnostics statistical conference in collaboration with the agency; the FDA is looking for comments on its TAP Pilot and published two warning letters for high-profile recalls.

Plastic Syringe Recall Update: 'More Widespread Then Originally Known'

The US Food and Drug Administration issued *three warning letters* to Chinese manufacturers producing and distributing unauthorized plastic syringes in the US.

The warning letters were sent on 18 March to the two marketing firms promoting the syringes, which are Medline Industries, LP and Sol-Millennium Medical, Inc., and the manufacturer Jiangsu Shenli Medical Production Co. Ltd.

It also inspected the Medline Industries and Sol-Millennium Medical, Inc. facilities, detained and inspected imported syringes at the border and lab-tested them.

"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," the FDA warned in the announcement.

As a result, the FDA updated its safety communication to recommend that suppliers, consumers, and health care organizations immediately switch to different syringes unless "absolutely necessary" during the transition.

The original safety communication was issued on 30 November, 2023 amid concerns over quality and potential device failures. (Also see "*FDA Evaluating Safety Of Plastic Syringes From China, May Prevent Their Import To The US*" - Medtech Insight, 5 Dec, 2023.)

The FDA told CNBC in January that in 2023, it had *more than 4,000 reports* related to plastic syringe malfunctions, not limited to ones made in China.

FDA And AdvaMed To Host Medical Device Statistical Issues (MDSI) Conference

The FDA will be collaborating with medical device trade group AdvaMed to host a public conference, from 2-3 April.

During the *FDA/AdvaMed Medical Device Statistical Issues (MDSI) Conference*, the agency will "share information on the recent and future developments of statistical methodology and practice in the evaluation of safe and effective medical products."

The conference, which will be held in Washington, DC, aims to promote innovations in clinical trials and advance statistics for diagnostics and medical devices.

Registration is open until 2 April on a first-come, first-served basis. The conference agenda can be found *here*.

FDA Posts A Pair Of Warning Letters Sent Earlier This Year

The FDA sent out warnings to two medical device firms in January for failing to adhere to good manufacturing practices and failing to establish procedures for implementing corrective and preventive procedures.

In the first letter *Fresenius Kabi AG - 671249 - 01/04/2024 | FDA* to Fresenius Kabi USA of North Andover, MA, dated 4 January, the FDA determined the firm was not in compliance with good manufacturing practice requirements as outlined in the agency's quality system regulations.

The device cited in the letter is the firm's Ivenix Infusion System, which includes the Ivenix Infusion Pump, Infusion Safety Management Software, and Intravascular Administration Set.

The FDA conducted its investigation of the firm's facility after the company initiated a recall of the pumps due to the potential for a leak shutting the devices down.

The warning stemmed from an investigation of the firm during August and September of last year. In its letter, the FDA said Fresenius Kabi failed to conduct a sufficient root cause analysis of a software glitch that led to a recall in September 2022.

The letter also cited the company's failure to verify its corrective and preventive action plan for a

leak, which led to another recall.

Fresenius Kabi initiated a recall in March, which is still ongoing.

Along with several violations listed in the letter, the agency's inspection also found that it misbranded Ivenix by failing to furnish the required material or information on the device.

Fresenius acquired Ivenix in April 2022 for $240m to expand its presence in the infusion pump market. (Also see "*Fresenius Kabi Acquires Ivenix For $240M To Expand Presence In Infusion Pump Market*" - Medtech Insight, 4 Apr, 2022.)

The FDA also sent a letter *Exactech, Inc. - 669904 - 01/19/2024 | FDA* to Gainesville, FL-based Exactech after an inspection of its facility in September 2023. According to the letter, the FDA found the firm's orthopedic devices, including the Equinoxe aTSA and Equinoxe rTSA, and accessories, for non-conformity to good manufacturing practices and failing to implement a sufficient CAPA.

As noted in both letters, the warnings are not intended to be an all-inclusive list of the violations at the facilities.

"It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA," the letters state.

Public Comment Period For Voluntary Total Product Life Cycle Advisory Program Pilot

The FDA is *collecting comments* on the data collection of its Total Product Life Cycle Advisory Program (TAP) Pilot.

The notice, posted 22 March, states that the agency is looking for comments specifically on the necessity and practicality of the proposed information collected in the program; the accuracy of the FDA's estimates of the burden of collection; ways to automate the information collection to ease the burden; and ways to enhance the quality of the data.

The voluntary TAP Pilot was launched in January 2023 as a part of the 2023-2027 Medical Device User Fee Amendments (MDUFA V). (Also see "*'Banner Year' For FDA's Device Center Includes Record Number Of Novel Authorizations*" - Medtech Insight, 18 Jan, 2024.)

The pilot is supposed to expedite the process of getting novel devices to patients by increasing communication between the FDA and medical device manufacturers.

Comments can be submitted under the *docket FDA-2024-N-1201* until 20 May.