

GEDSA Engaged with FDA and USTR – An Important Update

The Global Engineered Device Supplier Association (GEDSA) has been actively engaged with the U.S. Food and Drug Administration (FDA) regarding recent concerns over syringes that are manufactured in China. GEDSA has also been engaged with the Office of the United States Trade Representative (USTR) over a proposed 50% tariff on syringes imported from China.

A recent development in these matters came from the FDA's safety communication on August 16th, which addresses the evaluation of plastic syringes manufactured in China. In their communication, the FDA states, "*The FDA is not recommending a transition away from all enteral syringes manufactured in China at this time.*"¹

In an August 30th update from the office of the United States Trade Representative, it was communicated that the "*USTR continues to work to finalize the determination [of tariffs], and we intend to make it public in the coming days*"². The USTR initially expected to have their determinations communicated in August but has needed more time due to the overwhelming amount of public tariff comments they received, including comments from GEDSA³.

GEDSA has been closely monitoring the concern of the FDA and the USTR's proposed tariff. Our priority is to advance patient safety and by working with stakeholders across the healthcare spectrum we hope to ensure that the safest devices are readily accessible to patients and healthcare providers. We continue to advocate for clear, evidence-based guidance to minimize any disruptions to the global supply chain.

As the situation evolves, GEDSA will continue to work closely with key stakeholders, including the FDA and USTR, to ensure that our members and the broader healthcare community remain informed. We are also committed to sharing timely updates on any further developments that may impact patients.

For now, the key takeaway is clear: **the FDA is not recommending a transition away from all enteral syringes manufactured in China.**

¹ <https://ow.ly/CaY450TfQoy>

² <https://ow.ly/qPyU50Tkwbv>

³ <https://ow.ly/WWnw50TkzqF>

The Global Engineered Device Supplier Association (GEDSA™) is a 501(c)(6) non-profit trade association with the mission of advancing patient safety through engineered device solutions and initiatives that are coordinated among stakeholders spanning across the healthcare spectrum worldwide.