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FDA Hasn't Publicly Released A Device-Related Close-Out Letter For 5 Months, Defeating Purpose Of Program

by [Shawn M. Schmitt](#)

Medical device manufacturers under the dark cloud of a US FDA warning letter work hard to close them out, and, importantly, receive a close-out letter from the agency that is posted online for everyone to see. Yet FDA hasn't publicly released such a missive to device companies since May – the longest gap since the close-out program began in 2010. FDA says it's aware of the problem.

Are you a regulatory wonk who scours US FDA's website for up-to-date warning letter close-outs? Well, good luck finding any.

The agency has not released a device-related close-out letter for more than five months – the first time it has stopped posting such missives since FDA began handing them out in 2010.

FDA's close-out program publicly indicates when a manufacturer has addressed agency concerns outlined in a warning letter.

The last device-related close-out posted online was sent to Ropack Inc. on April 23, 2018. It was added to the agency's [close-out webpage](#) in May. (Also see "[Warning Letter Close-Outs – May 2018](#)" - Medtech Insight, 1 Jun, 2018.)

Since then there's been radio silence when it comes to close-outs – a potentially sticky wicket for industry given that device-makers work hard to close out warning letters and want public recognition for doing so.

A firm being "issued" a close-out letter isn't the same as having FDA publicly announce it online for the world to see – which, one could argue, is the whole reason behind the close-out program in the first place.

On Sept. 6, *Medtech Insight* reached out to FDA to find out why close-outs aren't being published. More than a month later, on Oct. 11, we received this email response from agency spokeswoman Deborah Kotz: "There has been no change to our policy or process for issuing warning letter close-out letters. Close-out letters have been consistently issued over the past six months at the same rate as they were issued for the six months prior to that. We are aware that the warning letter close-out webpage is not up-to-date, and we are working to resolve the issue."

Kotz noted that six device-makers were issued close-out letters that have not yet been posted online.

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When pressed to further explain what happened – why the close-outs aren't being posted – Kotz followed up with another email: "Don't know the details. I know these letters need to go through [the] FOIA office to get redacted before they're posted." (FOIA is the Freedom of Information Act.)

Medtech Insight has been tracking close-out letters since the very first one was publicly posted eight years ago. Below are the number released online each year since then:

- 2010: 11
- 2011: 37
- 2012: 62
- 2013: 56
- 2014: 49

- 2015: 90
- 2016: 61
- 2017: 47

So far this year, FDA has posted only six close-outs. When added to the six that have yet to be added online, the agency has sent a total of 12 close-out letters to firms in 2018 to date.

From the editors of The Gray Sheet