## MEDTECH INSIGHT

12 Oct 2018 | News

## QUOTED. Oct. 12, 2018. Deborah Kotz.

by

US FDA hasn't posted a device-related close-out letter online in five months. Agency spokeswoman Deborah Kotz says firms were "issued" close-outs over the past six months – they just haven't been posted online yet. But 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. See what else Kotz said here.

"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." –Deborah Kotz, spokeswoman, US FDA

• Find out more: <u>FDA Hasn't Publicly Released A Device-Related Close-Out Letter For 5 Months</u>, Defeating Purpose Of Program

**Click here** for a free trial of Medtech Insight