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FDA Misses Hoped-For May End Date For Problematic Summary Adverse Event Reporting Program

by Shawn M. Schmitt

The US agency is still taking steps to shutter its Alternative Summary Reporting Program, despite an earlier soft commitment to end it by the end of last month.

The US Food and Drug Administration is continuing to accept adverse event reports through its Alternative Summary Reporting Program, despite the agency's soft commitment to shutter the problematic program by the end of last month.

The ASR Program allows device-makers to submit abbreviated reports in a summarized, line-item format; it was established in 1997 in an effort by the agency to review adverse events more efficiently for well-established risks.

While a key goal of the program was to minimize duplicative reports that can overwhelm the FDA's surveillance activities, it also had the effect of keeping millions of safety reports hidden from the public.

> *"We plan to update the public on these efforts in the near future." – Michael Felberbaum*

The agency told *Medtech Insight* in mid-May that it is "in the process of working with all manufacturers who have ASRs to end the program. We anticipate this will be complete by the

end of the month." (Also see "*FDA Quietly Sunsetting Summary Reporting Program For Adverse Events, Readies Public Release Of Millions Of Pre-2017 Summarized MDR Reports*" - Medtech Insight, 16 May, 2019.)

But that didn't happen, and the agency's ASR Program *webpage is still active*.

"We are in the process of sunsetting the program," FDA spokesperson Michael Felberbaum confirmed in a 7 June email to *Medtech Insight*. "We plan to update the public on these efforts in the near future."

The FDA also said last month that it soon would publicly release summarized Medical Device Reports that were sent to the agency between 1998 and 2017. *That could number in the millions, according to a Medtech Insight count*.