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QUOTED. 30 April 2020. Terri Cornelison.

by

The US FDA will let Bayer AG roll up potentially thousands of adverse event reports about its problematic Essure birth control device into monthly spreadsheets. See what Terri Cornelison, director of the Health of Women Program within the agency's device center, had to say about the decision.

"Even though the device is no longer being manufactured or distributed, and hasn't been for some time, the FDA continues its engagement with Bayer on postmarket safety monitoring of Essure. Bayer alerted us to the social media information it received in connection with litigation. We are committed to ensuring that all reportable adverse events identified from this information are submitted to the agency and that they are made publicly available." – Terri Cornelison, director, Health of Women Program, CDRH

• Find out more: <u>Essure: FDA Grants Bayer Variance From MDR Reporting For Certain Adverse</u> <u>Events Found On Social Media</u>

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