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Essure: FDA Grants Bayer Variance From MDR Reporting For Certain Adverse Events Found On Social Media

The agency's move lets Bayer file only one 3500A reporting form a month for potentially thousands of events uncovered during litigation

by Shawn M. Schmitt

The US agency in a 24 April letter approved Bayer's request for a deviation from traditional Medical Device Reporting requirements. The variance applies to MDR-reportable events related to the problem-prone Essure device that Bayer is or becomes aware of from social media between November 2016 and November 2020, as part of ongoing litigation around the product.

The US Food and Drug Administration has given *Bayer AG* a green light to roll up potentially thousands of adverse event reports about its problematic – and now-defunct – Essure birth control device into monthly spreadsheets.

In a 24 April letter, the FDA approved Bayer's request for a deviation from traditional Medical Device Reporting requirements. The variance applies to MDR-reportable events related to Essure that Bayer is or becomes aware of from social media between November 2016 and November 2020, as part of ongoing litigation around the product.

The FDA granted the variance – effective from 24 April 2020 to 30 April 2021 – "because of the anticipated volume and nature of this information," the *agency said in a release*.

The FDA went on to say that it "continues to require that Bayer submit Essure-associated reportable events, outside of the events specifically covered in this variance, in accordance with current Medical Device Reporting requirements."

While Bayer stopped selling Essure in the US in December 2018 after a long string of medical mishaps, health care professionals were still allowed to continue implanting the devices through the end of 2019. The device is now completely off the market. (Also see "*Essure Update: Almost All Unsold Units Back To Bayer; Postmarket Study Enrollment Complete*" - Medtech Insight, 15 Jan, 2020.)

> *"Bayer alerted us to the social media information it received in connection with litigation." – Terri Cornelison*

"Even though the device is no longer being manufactured or distributed, and hasn't for some time, the FDA continues its engagement with Bayer on postmarket safety monitoring of Essure," said Terri Cornelison, director of the FDA's Health of Women Program within the agency's device center.

"Bayer alerted us to the social media information it received in connection with litigation," Cornelison said. "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."

Bayer's MDR variance says the company must:

- Submit a spreadsheet on a monthly basis that "includes all reportable events" that it is made aware of during that time. The firm must send its spreadsheets to the agency by the 10th of each month; for example, Bayer's first spreadsheet should arrive at the agency no later than 10 July, for events gathered during the month of June. The spreadsheet must include 26 specific items of information, from patient demographics and implant dates, to a description of events or problems, and more. The FDA says the spreadsheets will be made publicly available on its *Problems Reported with Essure* webpage.

- Attach a MedWatch 3500A reporting form to monthly spreadsheets. The form must include the total number of events by type (ie, death, serious injury, malfunction), and a patient or device problem code. It should also specify patient demographics and name the source of the report. Information on the device(s) involved and the entities that submitted the events should also be noted.

- Create adverse event analysis reports that analyze spreadsheet information quarterly, as well as cumulatively. The reports should include a "comprehensive analysis" of information from

> the MedWatch form, as well as the number of devices that were returned to Bayer. The firm should also provide summaries of any investigations it conducted in relation to returned devices. Further, the agency wants the company to include bar graphs in its reports that compare "trends for the events reported under this variance to trends for all other Medical Device Reports for Essure," the FDA's letter says. Further, a final analysis report that analyzes all adverse event data found during the yearlong variance must be sent to the agency no later than 29 July 2021.

The letter goes on to say that "Bayer intends to make each adverse event analysis report (quarterly and final) publicly available."

Despite the FDA's instructions in its 24 April letter to Bayer, a company statement released on the same day claimed that, "based on a representative sample, we believe that many of the reports contained in the social media documents have already been submitted to the FDA as MDRs and are consistent with Essure's known and labeled safety profile."

Nevertheless, "Bayer is committed to transparency, working with the FDA on this process, and making the results publicly available on a regular basis," the release said.

[Editor's note*: This article was updated on 27 April 2020 to include Bayer's response to the FDA's letter.*]