



Bayer U.S. LLC

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Bayer Statement on Essure Variance Letter from Food and Drug Administration (FDA)

WHIPPANY, N.J., April 24, 2020 – Bayer today released the following statement after receiving a variance letter from the Food and Drug Administration (FDA):

“On April 24, 2020, the FDA and Bayer agreed to a variance from Medical Device Reporting (MDR) requirements and timelines regarding a large number of social media documents the Company received in litigation. Bayer is committed to transparency, working with the FDA on this process, and making the results publicly available on a regular basis.

“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.

“The FDA cautions that MDRs may not contain enough detail to properly evaluate an event or determine if the event was due to the product. The agency has stated that ‘[a]lthough [MDRs](#) are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data.’ The FDA also states that ‘[t]he number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.’ Information from social media may present even more challenging limitations including reliability, duplication, volume, incomplete information, and lack of access to or ability to collect additional information.

“Bayer continues to stand behind the product’s safety and efficacy, which are demonstrated by an extensive body of research, undertaken by Bayer and independent medical researchers, involving more than 200,000 women over the past two decades. Women with Essure can continue to rely on it for their reproductive health and should speak to their healthcare providers if they have any questions or concerns.”

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Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting

efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.us.

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