Alerts and Recalls

Generic Name (Trade Nameâ€"Company)

April 12, 2018

Implanted birth control device

(Essure—Bayer)

FDA restricts sale and distribution of Essure, requires women to be informed of risks

Uses/Notes

FDA continues to monitor the safety of Essure. FDA stated that it continues to believe the benefits of the device outweigh its risks, and that Essure's updated labeling and the sales restriction will ensure that women are appropriately informed of the risks.

Some women have received the Essure device without being adequately informed of its risks. FDA has taken steps, including labeling changes in 2016 adding a boxed warning and patient decision checklist, to better inform health care providers and patients about these risks. For this device to meet reasonable assurance of safety and effectiveness, all women considering Essure should receive this important information.

On April 9, 2018, FDA restricted sales of the Essure device to only doctors and health care facilities who use the FDA-approved "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement," which is part of the patient information booklet. It includes key items about the device, its use, and safety and effectiveness outcomes. Sale and distribution of Essure is limited to health care providers who agree to review this checklist with patients, and give them the opportunity to sign it, before Essure implantation.

FDA also approved Bayer's new labeling that includes the following statement: "The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer."

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