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FDA Announces Plan to Speed Up Public Notification About Potentially High-Risk Device Recalls

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By: Nathan A. Brown, Olive Lee

On November 21, 2024, FDA's Center for Devices and Radiological Health (CDRH) announced a pilot program aimed at improving public notice about potentially high-risk medical device recalls.

The pilot seeks to reduce the time between FDA's initial awareness and public notification of corrective actions taken by companies for devices that FDA believes are likely to be high-risk recalls. These actions may include a company's removal of the product from the market, product corrections or updates to product use instructions to minimize high safety risks. The pilot will provide early alerts of company actions related to cardiovascular, gastrorenal, general hospital, obstetrics and gynecology, and urology devices. CDRH noted that there is no change to the recall process or recall communication timelines for other areas.

Based on the limited details in the announcement, it is unclear exactly how these early alerts will be communicated. Nor is it clear how FDA will have determined that a corrective action that a company has not proactively identified as a voluntary recall is indeed a recall (and not, for example, a device enhancement), and then reach a conclusion that it is likely to be Class I, which is the highest-risk class of recall. Typically, that conclusion is informed by information submitted by the recalling company that is then carefully evaluated by FDA.

FDA indicates that the pilot stems from recommendations from the Patient Engagement Advisory Committee, which advises FDA on complex issues involving the regulation of medical devices and patient use.

FDA will update its website with early alert communications as significant new information becomes available. Interested parties can also subscribe to CDRH's medical device safety and recalls email list here.

Categories

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