FDA Revised Guidance on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic

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The FDA revised its guidance on postmarket adverse event reporting for medical products and dietary supplements during a pandemic to apply the guidance to the ongoing COVID-19 pandemic. The FDA acknowledges that companies, and the agency, itself, may be hit with workforce shortages during a pandemic at the same time that adverse event reporting for products deployed for the pandemic may increase. Accordingly, the FDA says the aim of the guidance is to allow companies to "focus their limited resources" on submitting reports for products used against the pathogen causing the pandemic, as well as other specific reports identified in the guidance.

According to the Guidance, "normal adverse event reporting processes should be maintained to the maximum extent possible" during a pandemic, noting that companies should develop and implement a continuity of operations plan (COOP) to follow in the event of employee absenteeism. The FDA states that the guidance "is not intended to discourage adverse event reporting during a pandemic by firms that are able to continue reporting operations" and does not apply to reporting obligations for products authorized for emergency use or investigational products. The FDA says it does not intend to object to companies that are unable to submit adverse event reports to the agency within the required timeframes as a result of pandemic-related employee absenteeism, so long as they submit all delayed reports within six months of restoring their adverse event reporting processes "to their pre-pandemic state."

The FDA also advises companies to keep records of any adverse events that have been stored and document when their reporting processes are restored. FDA says there are some situations where it will expect companies to comply with normal reporting requirements during a pandemic, such as newly emerging product-related safety issues and product problems associated with adverse events.

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