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FDA urges to submit thorough, timely safety information for combination medical products

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"In the past decade we have seen a marked increase in interest from manufacturers who seek to develop medical products that combine devices, drugs and/or biologics. While there are many variations of these combination products, some of the most innovative are being created to deliver the correct dose of a drug to a precise part of the body at set times. This can lead to more targeted treatments that ensure patients receive correct dosages without the need to remember to take their medicine at a precise time," said FDA Principal Deputy Commissioner Amy Abernethy, M.D.

"But as this area has grown, so too has the need for information about the safety of these products when in routine use by patients. Today, the FDA is taking another step to help applicants better comply with important product postmarketing safety reporting requirements and provide us timely, comprehensive safety information about combination products at established intervals. We are issuing guidance, finalized today, that will help applicants better understand how to submit their combination product postmarketing safety reports. This guidance reinforces FDA's expectations for timely postmarketing safety information about combination products."

The U.S. Food and Drug Administration released a final guidance, "Postmarketing Safety Reporting for Combination Products," for applicants of combination products—products composed of two or more different types of medical products (i.e., drug, device or biologic)—to further clarify how they can comply with the 2016 final rule on postmarketing safety reporting requirements (PMSR) for combination products.

Although the PMSR regulations for drugs, devices and biological products have many similarities, each set of regulations establishes distinct safety reporting requirements, including standards and timeframes. This final guidance explains, among other things, which combination products are impacted by the PMSR requirements, how to submit reports, recordkeeping requirements, and how to avoid duplications when submitting safety information to the agency. This final guidance provides examples for both drug and device-led combination products with detailed flowcharts explaining which reports are required under the PMSR rule, and discusses the content for these reports, and when they are due to the FDA.

To ensure applicants have sufficient time to make necessary adjustments, the FDA announced in April that the agency does not intend to enforce the additional constituent part-based PMSR requirements until July 2020 for most combination products, and until January 2021 for vaccine combination product.