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QUOTED. 14 August 2019. Bradley Merrill Thompson.

by

Long-delayed changes to the US FDA's approach to postmarketing safety reporting for combination products are set to come into effect in 2020, following the agency's recent release of a final guidance document on the issue. See what Combination Products Coalition general counsel Bradley Merrill Thompson said about the guidance here.

"It appears that the FDA has addressed comments provided by industry on topics like follow-up reports, details to be included in the periodic safety reports, foreign events, same or similar devices and information-sharing responsibilities." – Bradley Merrill Thompson, general counsel, Combination Products Coalition

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