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Medical Device Update: Distinguishing Medical Device Recalls from Medical Device Enhancements

On October 15, the U.S. Food and Drug Administration (FDA) issued the final guidance "Distinguishing Medical Device Recalls from Medical Device Enhancements." This guidance revises and finalizes the draft version that generated significant controversy when it issued on February 22, 2013. The final guidance clarifies when a change to a device constitutes a medical device recall, distinguishes device recalls from device enhancements, and clarifies reporting requirements under 21 C.F.R. Part 806.

Controversy Regarding Part 806 Reporting Requirements for Device Enhancements

The most notable revision of the final guidance addresses a controversial recommendation in the draft guidance on Part 806 reporting requirements for recalls and device enhancements. When the draft guidance was issued in early 2013, it triggered significant industry comments and concerns because it stated that a "product enhancement" may be reportable under FDA's correction and removal reporting requirements at 21 C.F.R. Part 806.[1] This statement was made even though the draft guidance described a product enhancement as "a change to improve the performance or quality of a . . . non-violative device" and FDA's Part 806 reporting regulations require reports only if a correction or removal was initiated to "reduce a risk to health" or "to remedy a violation of the act caused by the device which may present a risk to health."[2] In response to industry members' concerns, the final guidance deletes the section on product enhancement reporting requirements and states instead that "[m]edical device enhancements do not require the submission of an 806 report."

Final Guidance Clarifies Difference Between Recalls and Device Enhancements

The primary purpose of the final guidance is to distinguish recalls from device enhancements. The guidance states that a recall can be any correction or removal of a device that has been distributed when the device is in violation of the Federal Food, Drug, and Cosmetic Act and/or FDA regulations and the violation is one against which the FDA would initiate legal action. By contrast, a product enhancement is a "change or improvement to a non-violative device as part of continuous device improvement activities." To illustrate the difference between a recall and a device enhancement, the final guidance includes several examples that follow the definition of each term. Examples are provided for various types of devices, including in vitro diagnostic (IVD) devices. For example, the FDA clarifies that a modification to improve the sensitivity of an IVD from 95% to 98% when there is no known violation is a device enhancement, but that a modification to "improve" the sensitivity of an IVD device that does not meet the sensitivity it is represented to have (e.g., 95%) is a recall.

Regarding the reporting of recalls to the FDA, the final guidance states that a recall must be reported under Part 806 if the violation that triggered the recall "may present a risk to health" and has not already been reported to the FDA under 21 C.F.R. Part 803 or 1004. Although the draft guidance included factors to consider in determining when a recall may present a "risk to health," the FDA's more streamlined final guidance does not include this discussion. The final guidance also deletes the draft guidance section on factors that FDA considers in assessing the degree of health hazard and the recall decision-making chart.

1. The final guidance uses the term "device enhancement" instead of "product enhancement."
2. 21 C.F.R. § 806.10.

Morgan Lewis

Contacts

If you have any questions or would like more information on the issues discussed in this update, please contact any of the following Morgan Lewis lawyers:

Washington, D.C.

M. Elizabeth Bierman	+1.202.739.5206	mebierman@morganlewis.com
Phoebe Mounts	+1.202.739.5898	pmounts@morganlewis.com
Anthony “Tony” Pavel	+1.202.739.5612	apavel@morganlewis.com
Michele L. Buenafe	+1.202.739.6326	mbuenafe@morganlewis.com

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