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Food, Drug & Device Law Alert - FDA Issues Final Guidance On Distinguishing Medical Device Recall From Product Enhancement

October 21, 2014 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently issued a final guidance document titled, “Distinguishing Medical Device Recalls from Medical Device Enhancements.” According to the FDA, the guidance is intended to resolve industry confusion over when a change to a marketed product amounts to a recall, and thus triggers certain reporting requirements, or is merely non-reportable product improvements.

The guidance wastes no time in identifying the key distinction between a recall and an enhancement in FDA’s view. In the first paragraph of the introduction, the FDA states:

> FDA defines a device recall by regulation as a firm's removal or correction of a marketed device that the Agency considers to be in violation of the laws that it administers and against which the agency would initiate legal action, e.g., seizure. 21 CFR 7.3(g). *The key factor in distinguishing a medical device recall from an enhancement is the existence of a violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 360h] or associated regulations enforced by the Agency.*

(Emphasis added). Later, however, the guidance introduces some ambiguity by stating that the definition of a recall only covers changes made to address violations “against which the agency would initiate legal action.”

After some brief background, the guidance includes a section defining several of the key terms in this area, such as recall, correction, removal, market withdrawal, violation or violative, device enhancement, stock recovery, market withdrawal, and routine servicing. Apart from the definitions of device enhancement and routine servicing, the other definitions are simply rehashes of the existing regulations. The guidance also provides examples of each category, but the examples are largely black-and-white, with the correct resolution being apparent to anyone who read the introduction as soon as the example states whether or not a violation is involved. Thus, the guidance is not likely to satisfy those who were critical of the draft version because it did not address long-standing interpretation issues with the regulations.

The guidance then includes sections in question and answer format to help in identifying recalls. The questions addressed include:

1. Is the product a “device?”
2. Are you considering making a correction to or removal of the

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Lynn C. Tyler, M.S.
Partner
Indianapolis

P 317-231-7392
F 317-231-7433
lynn.tyler@btlaw.com

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device?
3. Are you currently marketing the device?

A yes answer to each of these points to a recall. Key questions on whether the change involves a violation or not include:

1. Are the changes intended to resolve a failure to meet specification or to perform as represented?
2. Is the labeling for the device false or misleading, does it fail to bear adequate directions for use, or does it otherwise violate the FD&C Act or FDA regulations?
3. Are you otherwise in compliance with FDA's regulations?

Affirmative answers to the first two questions point to a recall. A negative answer to the third question suggests a recall, although the guidance does state "the addition of a new warning or other changes to the labeling of a *non-violative* device would not meet the definition of a recall" (FDA's emphasis).

The draft version of this guidance was issued in February 2013 and was widely criticized. FDA made several changes in response to the criticism, which had the effect of cutting the length of the guidance almost in half. The final guidance did add several examples compared to the draft version. The final version removed some ambiguity from the definitions of correction and removal which had suggested that a correction or removal could be a recall or an enhancement, depending on the circumstances.

The final guidance removed a widely-criticized sentence that "reports of correction and removals under 21 CFR Part 806 may be required for corrections and removals regardless of whether the implemented change meets the definition of a medical device recall." Under the final guidance, a firm must only submit a report if the correction or removal was done to address a risk to health. If a correction or removal was not implemented to resolve a risk to health, the firm only has to keep records of the action for two years. A report is not required for a product enhancement.

A copy of the guidance can be found here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device Group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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