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Client Alert

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FDA Issues Draft Guidance on Medical Device Recalls
How to Distinguish Recalls from Product Enhancements

On February 22, 2013, the U.S. Food and Drug Administration (FDA) released a long-anticipated draft guidance document entitled *Distinguishing Medical Device Recalls from Product Enhancements; Reporting Requirements*.[1] With the draft guidance, FDA intends to clarify how to determine whether a change made to a marketed medical device should be considered a recall or a product enhancement and whether the recall or product enhancement should be reported to FDA. Comments on the draft guidance must be submitted by May 23, 2013 via mail or electronically through Regulations.gov. All comments should identify docket number FDA-2013-D-0114.

The draft guidance is intended to help manufacturers to answer two questions: (1) whether a change to a medical device constitutes a recall or a product enhancement, and (2) whether the change to the device must be reported to FDA. FDA acknowledges that manufacturers often undertake continuous improvement activities related to medical devices. These changes "often have a favorable impact on medical device safety and are part of ongoing efforts to design and manufacture devices that meet the needs of the user and patient." FDA does not want to discourage these improvements and recognizes that not all such changes necessarily constitute a recall. However, when such product enhancements are made to improve the safety of the device, the product enhancements may nevertheless need to be reported under the corrections and removals requirements of 21 C.F.R. Part 806.

The draft guidance is arranged in a question and answer format separated into sections regarding (i) definitions, (ii) recall identification, (iii) differentiating violative devices from non-violative devices, (iv) recall reporting requirements, and (v) product enhancement reporting requirements. The draft guidance also contains a flow chart to aid firms in determining whether an action constitutes a recall or product enhancement. The guidance does not address whether a change made to a marketed device that is considered either a recall or product enhancement would require the filing of a PMA supplement or a 510(k).

Definitions

The definitions section provides a definition of "product enhancement" and makes clear that a product enhancement is not a recall.[2] FDA defines product enhancement as "a change or improvement to a non-violative device as part of continuous device improvement activities." Under this definition, a change to a marketed device is considered a product enhancement, and not a recall, if the change (a) improves the performance or quality of a device, and (b) is not made to correct a violation of FDA law or regulation.

The guidance provides the following examples of changes that would be considered product enhancements:

- changes designed to better meet the needs of the user,
- changes to make the product easier to manufacture, and
- changes to the appearance of the device that do not affect its use.

Even though a product enhancement is not a recall, it nevertheless may be reportable under 21 C.F.R. Part 806. The reporting requirements are addressed further in the Product Enhancement Reporting Requirements section of the draft guidance and of this client alert.

All other terms defined in the draft guidance—recall, stock recovery, market withdrawal, correction, and removal—have the same definitions as in current FDA regulations at 21 C.F.R. sections 7.3 and 806.2.

Recall Identification

The first three questions FDA identifies as being necessary to determine whether a manufacturer may be undertaking a recall are:

- Is the product a device?
- Are you considering making a change to the device?
  - FDA states that changes to the device include changes to the device design, manufacturing process, labeling, and marketing practices.
- Are the devices that you are considering changing on the market?

If the answer to all three questions is yes, then the manufacturer must next consider whether the change is being made to a violative device or a non-violative device. This is important because, as the draft guidance explains, "the significant distinction between a medical device recall and a product enhancement is the reason for changing the medical device." If the change is made to address a violation of FDA law or regulations, then the change constitutes a recall, as explained below.

Differentiating Violative Devices from Non-Violative Devices

FDA provides guidance for how to differentiate violative and non-violative devices, an important distinction because changes made to non-violative devices are considered product enhancements and are not recalls. Only changes that are made "to remedy a violation of the laws administered by FDA and against which the agency would initiate legal action" constitute recalls.

In the draft guidance, FDA explains that devices that (a) fail to meet specifications, or (b) fail to perform as intended are considered violative devices; FDA would consider such devices to be adulterated because they are "of a quality below what they purport or are represented to possess." Changes to correct these problems would be considered recalls. On the other hand, changes made to improve the performance or quality of a device "do[] not typically mean that the underlying product was violative" if the changes were made "to improve a level of safety performance that was known, predicted, and stable at the time the device was cleared or approved." This statement in the draft guidance suggests that FDA expects that all three conditions must be met before a manufacturer determines that a change in the device or its labeling to improve the level or safety or performance is not a recall and is instead considered a product enhancement. Even if such safety-related improvements are not recalls, these changes may be reportable as corrections or removals, as described below.

In addition, changes made to correct false or misleading aspects of a device's labeling are considered recalls because the false or misleading statements render the products misbranded and are therefore violative devices. FDA applies its standard definition of labeling to include materials such as brochures, instruction manuals, posters, circulars, and websites. FDA notes that although changes made to a device's label that do not correct false or misleading statements are not recalls, they may still be reportable as corrections, for example, if the change adds a new warning.

Recall Reporting Requirements

If a device manufacturer determines that it has made a change to a marketed medical device to correct a violation of FDA law or regulations, including corrections such as changes to the instructions for use, it must determine whether the recall is reportable. FDA explains that a recall must be reported to FDA under 21 C.F.R. Part 806 (Medical devices; reports of corrections and removals) "as long as the violation targeted by the recall may present a risk to health."[3] As defined in the draft guidance and 21 C.F.R. § 806.2(j), risk to health means:

> (1) a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) that use of or exposure to the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

FDA recommends conducting an analysis or assessment of the risk to health associated with the device change or defect. This can be accomplished by conducting a health hazard evaluation (HHE). The draft guidance refers firms to the factors identified in 21 C.F.R. § 7.41 for consideration when conducting an HHE and also identifies additional factors that FDA considers when assessing the likelihood of adverse health consequences.

Product Enhancement Reporting Requirements

Finally, the draft guidance explains when a change to a device would be considered a product enhancement but would still need to be reported to FDA under Part 806. Specifically, changes to non-violative devices that reduce a risk to health posed by the device must be reported to FDA under Part 806, even if the changes do not constitute recalls. FDA's examples of such changes are "the addition of a new warning to a device's label in order to reduce a health risk, a manufacturing change to a sterile device to reduce the likelihood of contamination, or a design change to improve a product's safety profile." Any such product enhancements reported to FDA under Part 806 should be identified by the manufacturer as a product enhancement. According to the draft guidance, "if FDA concurs with . . . [the firm's] assessment that the correction or removal is a product enhancement, the agency will not treat the

report as a recall but will determine the appropriate premarket and postmarket actions necessary to address the information contained in the 806 report."

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Potential Impacts of the Draft Guidance

Although FDA states that its draft guidance is intended to clarify existing requirements related to recalls and Part 806 reports, the requirement to report certain product enhancements under Part 806 may be surprising to many medical device manufacturers. Previously, many firms did not consider safety-related improvements to be reportable corrections or removals if the improvements were not required to address a specific risk to patient health that became known after the device was placed on the market. This is especially true of changes to device labels made to strengthen existing or add new warnings. However, with this draft guidance, FDA clarifies that such changes may be reportable under Part 806. FDA bases this interpretation on the requirement in 21 C.F.R. § 806.10(a) that manufacturers submit Part 806 reports for corrections or removals that are initiated "[t]o reduce a risk to health posed by the device." Under FDA's interpretation, any steps taken to improve the safety of a marketed device could be considered product enhancements that were initiated to reduce a risk to health, due to the logical inference that changes made to increase safety will reduce risks to health. Manufacturers should be aware of this requirement and may need to update processes and procedures regarding design changes and reporting of corrections and removals.

If you are interested in submitting comments to FDA regarding this draft guidance and would like assistance from King & Spalding, please let us know. We will continue to monitor FDA regulations and guidance regarding medical device recalls as well as the status of this draft guidance.

[1] 78 Fed. Reg. 12329 (Feb. 22, 2013).
[2] FDA defines "recall" in the draft guidance and in 21 C.F.R. § 7.3(g) as "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery."
[3] This aligns with the requirement in 21 C.F.R. § 806.10(a) to report corrections and removals that are taken to (a) reduce a risk to health or (b) remedy a violation that may present a risk to health.