

Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Final Medical Device Recalls Guidance *Explains How to Distinguish Enhancements from Recalls*

On October 15, 2015, the U.S. Food and Drug Administration's Center for Devices and Radiological Health ("CDRH") issued a final guidance document, *Distinguishing Medical Device Recalls from Medical Device Enhancements* ("Final Recalls Guidance").¹ The guidance follows and revises a draft guidance document, *Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements*, issued on February 22, 2013 ("Draft Guidance").²

Like the Draft Guidance, the Final Recalls Guidance is intended to clarify: (1) when a change to a device constitutes a recall; (2) the difference between a medical device enhancement and a recall; and (3) reporting requirements under 21 C.F.R. Part 806. The Final Recalls Guidance does not address when a change to a device (whether an enhancement or recall) requires an additional premarket submission, though it does emphasize that this determination should be made separately from the analysis of whether a change to a device is a recall. Although the primary content and focus of the Final Recalls Guidance remains unchanged from the Draft Guidance, there are some notable differences, which we describe in more detail below.

Key Differences Between the Final Recalls Guidance and Draft Guidance

The most significant change from the Draft Guidance is the elimination of a recommendation to report safety-related changes to non-violative devices under Part 806. The Draft Guidance contained a section titled "Product Enhancement Reporting Requirements" that recommended reporting under Part 806 for device and/or labeling changes that were initiated to reduce a risk to health, even when the device at issue was not violative. This section has been eliminated in its entirety in the Final Recalls Guidance. FDA has abandoned this recommendation, which would have broadened the scope of expected reporting under Part 806; the Final Recalls Guidance explicitly states: "Medical device enhancements do not require the submission of an 806 report."³

In addition to eliminating the recommendation to report safety-related changes made to non-violative devices, FDA streamlined the guidance document, focusing only on the core issue of distinguishing medical device

For more information, contact:

Pamela F. Forrest

+1 202 661 7888

pforrest@kslaw.com

Elaine H. Tseng

+1 415 318 1240

etseng@kslaw.com

Steven Niedelman

+1 202 626 2942

sniedelman@kslaw.com

Beverly H. Lorell, MD

+1 202 383 8937

blorell@kslaw.com

Jessica M. Ringel

+1 202 626 9259

jringel@kslaw.com

King & Spalding

Washington, D.C.

1700 Pennsylvania Avenue, NW

Washington, DC 20006-4707

Tel: +1 202 737 0500

Fax: +1 202 626 3737

San Francisco

101 Second Street

Suite 2300

San Francisco, CA 94105

Tel: +1 415 318 1200

Fax: +1 415 318 1300

www.kslaw.com

enhancements from medical device recalls. In doing so, FDA removed several additional sections of the Draft Guidance, but did not change its interpretation of the basic difference between enhancements and recalls: recalls are conducted for changes to violative products, whereas enhancements are conducted for changes to non-violative products. The additional sections that FDA deleted from the Draft Guidance were ancillary to that central concern. Specifically, FDA deleted long discussions of (1) how to determine if the violative product presents a risk to health (as is necessary to determine whether a recall must be reported to FDA under Part 806) and (2) the factors that FDA uses when reviewing a manufacturer's evaluation of the risk to health. Neither of these topics helped to distinguish an enhancement from a recall, but rather were important to the determination of whether a report of a recall was required under Part 806. FDA also removed a recall decision-making flow chart that was in the Draft Guidance and did not provide a revised decision-making flow chart in the Final Recalls Guidance to assist manufacturers in determining whether an action constitutes a device enhancement or a recall.

The Final Recalls Guidance is written in a Question and Answer format and provides instructive examples of scenarios that FDA considers either to be medical device enhancements or medical device recalls. These examples illustrate FDA's current interpretation of the distinction between a device enhancement and a recall.

Definitions and Examples

Section IV of the Final Recalls Guidance contains definitions with useful examples that were not in the Draft Guidance. FDA has not changed the definitions of key terms from the Draft Guidance. A medical device enhancement (previously referred to as a "product enhancement") continues to be defined as "a change to improve the performance or quality of a device that is . . . not a change to remedy a violation of the [Food, Drug, and Cosmetic] Act [FD&C Act] or associated regulations enforced by the Agency."⁴ FDA notes that these enhancements include "changes designed to better meet the needs of the user, changes to make the device easier to manufacture, changes to improve a non-violative device's safety or performance, and changes to the appearance of the device that do not affect its use."⁵

The Final Recalls Guidance adds two terms to the definitions section that were not defined in the Draft Guidance: "violation or violative" and "routine servicing." FDA defines "violation" and "violative" to mean that "the device does not comply with the FD&C Act or associated regulations enforced by the Agency."⁶ "Routine servicing" is "any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy"⁷ The Final Recalls Guidance specifies that routine servicing is not a recall, and neither are stock recoveries or market withdrawals.

Section IV also includes several hypothetical device changes that would be considered recalls, corrections, removals, enhancements, stock recoveries, or market withdrawals and that demonstrate real-world applications of the definitions. These examples highlight the differences between changes to devices that are considered recalls and those that are not. In all of the recall examples, the product fails to meet its specifications or otherwise does not perform as represented, whereas the products in the device enhancement examples are not associated with failures to meet specifications or safety or effectiveness concerns. For example, FDA describes two similar scenarios involving an in vitro diagnostic device ("IVD") that is represented to have 95% sensitivity. In one scenario, the manufacturer modifies the IVD to improve the sensitivity to 98%. This change would be considered a medical device enhancement because "the modification is determined to be an improvement to the safety and effectiveness of the device, and is determined to be unrelated to any known device violation."⁸ In an alternate scenario, after the sensitivity of the device drops to 90%, the firm changes the product in the field to return the sensitivity to 95%. In this case, the action is a recall, because the product was violative by virtue of a failure to meet its performance specifications and because "the firm's actions are returning the product to the quality it was represented to possess."⁹

Recall Identification

Section V contains three baseline questions that should be answered before determining whether an action constitutes a recall: (1) whether the product is a device, (2) whether a change to the device (that is, a possible correction or removal) is being considered, and (3) whether the device is currently marketed. FDA lists the following as common types of post-market changes that could be considered a recall, if taken to correct a violative device: design changes, labeling changes and updates, and updated marketing materials. With regard to question 3, a footnote in the Final Recalls Guidance explains that “devices distributed for use in a clinical study under an Investigational Device Exemption (IDE) are not considered to be marketed.”¹⁰

Differentiating Violative Devices from Non-Violative Devices

Section VI of the Final Recalls Guidance contains important guidance on how to differentiate violative from non-violative devices and thereby differentiate device recalls from device enhancements. Similar to the Draft Guidance, the Final Recalls Guidance explains that “[c]hanges intended to resolve a failure to meet specifications or failure of the device to perform as represented would generally constitute recalls.”¹¹ FDA considers such devices to be adulterated because they are of a lesser quality than the quality they purport or are represented to possess. Additionally, as in the Draft Guidance, FDA notes that increases in rates of overall failures and single mode failures, along with the identification of new failure modes, may suggest that the device is failing to perform as represented; therefore any changes to address these failure modes would be considered recalls (and not device enhancements).¹² FDA provides two variations on each of two hypotheticals (one involving a battery-powered implantable device and one involving an infusion pump display) that distinguish between changes made to improve a device beyond its stated specifications and those made to return a device to its specifications, the latter changes constituting recalls.

FDA notes that a change intended to correct labeling that is false or misleading, fails to provide adequate directions for use, or otherwise violates FDA labeling law and regulations would generally be considered a recall. On the other hand, labeling changes to non-violative devices and non-violative labels (including the addition of a new warning) would not be considered recalls; nothing in the Final Recalls Guidance suggests that a Part 806 report is required for such labeling changes for non-violative products. This is a significant departure from the Draft Guidance, in which FDA recommended that manufacturers file Part 806 reports for changes that reduce a risk to health, even when the device and label were both non-violative. Because the addition of a new warning would likely be considered a labeling change that was taken to reduce a risk to health, the Draft Guidance would have recommended the filing a Part 806 report, even when the device and label were both non-violative. This is no longer the case under the Final Recalls Guidance.



King & Spalding will continue to monitor FDA guidance and policy regarding medical device recalls. Please contact us if you would like assistance applying the Final Recalls Guidance to your policies or procedures.

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¹ Available at

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM418469.pdf>.

² King & Spalding's Client Alert on the draft guidance is available at

<http://www.kslaw.com/imageserver/KSPublic/library/publication/ca022813.pdf>.

³ Final Recalls Guidance at p 7.

⁴ *Id.* at p 4.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.* at p 5; *see also* 21 C.F.R. § 806.2(l).

⁸ *Id.* at p 4.

⁹ *Id.* at p 3.

¹⁰ *Id.* at p 5, fn 8.

¹¹ *Id.* at p 6.

¹² *Id.*