



Welcome to today's **FDA/CDRH Webinar**

*Thank you for your patience while we register all
of today's participants.*

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FDA Guidance Document: *"Distinguishing Medical Device Recalls from Medical Device Enhancements"*

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Objectives

- Emphasize that the key factor in distinguishing a medical device recall from an enhancement is the existence of a violation of the Food Drug and Cosmetic Act (FD&C Act)
- Understand that correctly categorizing a change to a device as a recall or an enhancement impacts the applicability and nature of industry responsibilities and FDA oversight
- Provide guidance and examples to facilitate the decision-making process for when a Report of Correction and Removal (806 report) to the Center for Devices and Radiological Health (CDRH) would be necessary

Feedback from Industry

- **Concerns about making modifications to devices**
 - Does enhancing a device cause existing devices to become violative?
 - Will the FDA request a recall?
 - When is a change an enhancement and when is it a recall?
 - What needs to be reported to the FDA?

Comments on Draft Guidance

1. Clarification of definitions;
2. Request for more examples; and
3. Clarification of reporting obligations pertaining to Medical Device: Reports of Corrections and Removals (21 CFR Part 806)

Recurring Themes – Public Comments on Draft Guidance

- Stock recovery
- Increase number of examples given
- Remove flowchart
- Withdraw guidance
- Point of use
- Rulemaking
- Subjective
- Applicability to future devices
- Technical violations

14 responses (containing 111 comments) were received:
4 from trade associations, 10 industry

Key Points

This guidance is intended to:

1. Clarify when a change to a device constitutes a medical device recall,
2. Distinguish those instances from device enhancements that do not meet the definition of a medical device recall, and
3. Clarify reporting requirements under Medical Device: Reports of Corrections and Removals (21 CFR Part 806)

Important factors

- It is important to note that this guidance **does not alter** our current expectations regarding medical device recalls
- It applies to **medical devices regulated by CDRH**, whether or not devices require or are exempt from premarket review
- This guidance **seeks to address concerns** that firms may have about making enhancements

Factors that do not apply

This guidance does not address and does not apply to:

- Whether a new premarket submission is required
- Radiation-emitting electronic product defects or failures to comply with radiation safety performance standards contained in 21 CFR Parts 1020 to 1050
- Methodologies for risk management or risk assessment

Recall Definition

- As defined at 21 CFR 7.3(g), “recall means a firm's removal or correction of a marketed device 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.”
- Recall does NOT include routine servicing.
- Recall also does NOT include an enhancement, as defined by this guidance.

Enhancement Definition

- A device enhancement is
 - (1) a change to improve the performance or quality of a device; that is
 - (2) *not* a change to remedy a violation of the FD&C Act. Device enhancements include, but are not limited to, changes designed to better meet the needs of the user, changes to make the device easier to manufacture, changes to improve the device's safety or performance, and changes to the appearance of the device that do not affect its use.

Recall Identification

Firms should consider:

- Is your product a device?
- Why are you considering making a change to your device?
- Are you currently marketing the device to which you are considering or making changes?

What is the Violation?

- The key factor in distinguishing a medical device recall from an enhancement is the existence of a violation of the FD&C Act.

Differentiating Violative Devices from Non-Violative Devices

- Are the changes intended to resolve a failure to meet specifications or failure of the device to perform as intended?
- Is the labeling for the device to which you are considering making changes false or misleading; does it fail to have adequate directions for use; or does it otherwise violate the FD&C Act or FDA regulations?
- Are you otherwise out of compliance with FDA regulations?

806 Reporting Requirements

- Medical device enhancements do not require the submission of an 806 report

Other Regulatory Considerations

- Once a determination has been made, whether the change represents a medical device recall or an enhancement, additional regulatory obligations should be considered.

Comparison Example #1

Recall

- An in vitro diagnostics (IVD) device firm markets a test to detect the level of a specific antigen in blood. The device represents 95% sensitivity to the specific antigen.
- Two years after initial marketing, the firm determines that the device sensitivity to the specific antigen, as manufactured, has decreased to 90%, thus not meeting performance specifications and making the device violative.
- As a result, the firm modifies the product in the field to “improve” the sensitivity from 90% to 95%. Because the firm’s actions are returning the product to the quality it was represented to possess, FDA would generally consider these actions a recall.

Comparison Example #1

Enhancement

- An IVD device firm markets a test to detect the level of a specific antigen in blood. The device is represented to have 95% sensitivity to the specific antigen.
- Two years after initial marketing, the firm modifies the product to improve the sensitivity to the antigen from 95% to 98%. This 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.
- FDA would generally regard this action as a device enhancement, although it may require a regulatory submission.

Comparison Example #2

Recall

- Shortly after launch, the ergonomics of a marketed electrosurgical unit device are determined to be less-than-optimal, in that users have reported difficulty guiding the hand piece and the firm has received reports of serious injury associated with its use.
- The firm's investigations reveal that difficulty guiding the hand piece contributes to the serious injuries and that the hand piece is not performing as represented.
- The firm replaces all the hand pieces in the field and on all units currently in inventory, to eliminate the possibility of serious harm.
- FDA would generally consider these actions a recall.

Comparison Example #2

Enhancement

- A firm markets a new electrosurgical unit device. Shortly after launch, the ergonomics of the hand-piece of the newly-marketed device are determined to be difficult to use.
- The firm determines that this difficulty does not change the risk of the device and no violations of the FD&C Act or regulations are identified.
- The firm develops and incorporates a new hand piece into the electrosurgical unit device.
- FDA would generally consider this action to be a device enhancement, although it may require a regulatory submission.

Summary

- **Correctly categorizing medical device recalls and medical device enhancements:**
 - amplifies the likelihood that firms will appropriately determine when 806 reports to CDRH are and are not necessary; and
 - increases the likelihood that FDA will concur with industry decisions regarding reporting obligations.
- **The guidance:**
 - provides added clarity to regulatory terms and definitions specific to medical device recalls and enhancements; and
 - does not intend to address the comprehensive obligations related to medical device recalls.



Questions?

For general questions, contact the Division of Industry and Consumer Education: DICE@fda.hhs.gov

For more specific questions, please contact your district office:

<http://www.fda.gov/safety/recalls/industryguidance/ucm129334.htm>

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