FDA Draft Guidance on Device "Product Enhancements" Could Lead to Increased Recalls

On February 22, 2013, the Food and Drug Administration ("FDA") issued draft guidance explaining when a change to a medical device constitutes a medical device recall as opposed to a "product enhancement." This draft guidance has the potential to increase the number and frequency of recalls. Device manufacturers should pay close attention to FDA's proposed changes in this area, as litigation and government investigations alleging violations of recall-related regulations have been increasing.

Newly Created Term – "Product Enhancement"

FDA regulations define a recall as the "removal or correction of a marketed product that [FDA] considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. § 7.3(g). The term "product enhancement" does not appear in FDA regulations, but is defined in the draft guidance to mean a change to improve the performance or quality of a device that does *not* remedy a violation of the Food, Drug, & Cosmetic Act ("FDCA").

The draft guidance sets forth a decision-making flow chart for distinguishing medical device recalls from product enhancements by asking such questions as:

- *Is the device to be changed failing to meet any specification or failing to perform as intended?*
- *Is the labeling for the device to be changed false or misleading, does it fail to have adequate directions for use, or does it otherwise violate the FDCA or FDA regulations?*
- *Is the device otherwise out of compliance with FDA regulations?*

Where the answer to any of these questions is yes, the draft guidance suggests that the action is a recall and not a product enhancement.

Draft Guidance Would Set a Low Bar for What Constitutes a "Recall"

The draft guidance appears to set a low bar for deeming a change to a product to be a recall as opposed to a product enhancement. For example, FDA asserts that "if a device is being corrected to address a Quality System [Regulation] violation . . . the correction would generally be considered a recall." While some medical device manufacturers might have interpreted the regulations this way in the past, others may find this to be a significant shift from past practice.

The draft guidance also fails to provide any meaningful explanation of how a manufacturer is supposed to determine whether a violation is one that would trigger FDA legal action. FDA regulations use the term "market withdrawal" to mean a "minor violation [of the FDCA] that would not be subject to legal action by the FDA." Market withdrawals are excluded from the definition of a recall. Although the draft guidance repeats this definition, it elaborates on neither the substantive criteria, nor the process by which manufacturers are expected to make this determination. In addition, the recall decision-making flow chart included in the draft guidance omits the market withdrawal option altogether. By taking this approach, the draft guidance fails to address key questions that device manufacturers face.

Reporting Requirements

Unlike for other FDA-regulated product types, medical device recalls are subject to mandatory "Part 806" reporting to FDA if the correction or removal was undertaken to remedy a violation of the FDCA that "may present a risk to health." The draft guidance explains these existing requirements and also clarifies that a change that constitutes a product enhancement may be subject to Part 806 reporting if the change is initiated to reduce a risk to health, even if the device is fully compliant with the FDCA. Examples of such reportable product enhancements include adding a warning to a device's label to reduce a health risk, changing the sterilization process for a device to reduce the likelihood of contamination, or making a design change to improve a product's safety profile.

Consequences for Medical Device Manufacturers

The draft guidance may be of concern to manufacturers because of the low bar it appears to set for defining a product change as a recall rather than a product enhancement. The number of Class I recalls of medical devices increased each year from 2009 to 2012, probably as a result of FDA "up-classifying" recalls to Class I that in the past would have been Class II. FDA publicly discloses such recalls, which can negatively affect a company's reputation and, in some instances, attract litigation. In addition, device manufacturers are increasingly facing whistleblower-initiated lawsuits and government investigations alleging violations of the civil False Claims Act for failure to comply with Part 806 reporting requirements and conducting "stealth recalls."

Moreover, in early 2010, FDA's Center for Devices and Radiological Health ("CDRH") disclosed the existence of a "corrective fix" pilot program whereby some manufacturers were required to recall older devices after the CDRH approved or cleared product improvements. The draft guidance does not address whether a change triggers a requirement to submit a new 510(k) premarket notification or premarket approval supplement to FDA. Where such a premarket submission is required, however, manufacturers should be prepared for FDA scrutiny of whether the proposed change constitutes a recall or product enhancement.

FDA will be accepting comments on the draft guidance until May 23, 2013. For more information, please contact a member of Ropes & Gray's FDA regulatory team or your regular Ropes & Gray attorney.