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New FDA Draft Guidance on Voluntary Recalls Asks: Are You Prepared?

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On April 24, 2019, the Food and Drug Administration ("FDA") released a draft guidance, entitled "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C," to provide additional guidance to industry regarding timely initiation of voluntary recalls of FDA-regulated products. The draft guidance stresses the importance of being "recall ready" and recommends preparations that manufacturers and distributors should take to facilitate timely voluntary recalls.

As described in more detail below, much of the draft guidance echoes FDA's long-established recall "guidelines" in 21 C.F.R. Part 7.[1] Although both the draft guidance and the Part 7 guidelines upon which it is based are legally non-binding, the draft guidance helpfully cross-references related regulations that are mandatory for particular FDA-regulated product categories (e.g., field alert reporting for drugs under 21 C.F.R. § 314.81(b)(1), correction and removal reporting for medical devices under 21 C.F.R. § 806.10, and investigating failures and nonconformities for drugs and medical devices under 21 C.F.R. §§ 211.192, 820.100(a)(2)). Additionally, the draft guidance provides new recommendations for firms related to training and the development of recall-related SOPs.

Recommendations for Becoming Recall Ready

Identification and Training of Personnel. The draft guidance recommends that specific employees be assigned recall-related responsibilities and possess the necessary authority to perform such responsibilities when needed. FDA explains that establishing a designated "recall team" may be appropriate for firms that anticipate complex recall efforts, such as firms with a large or multi-layered distribution chain. The draft guidance also recommends training the recall-responsible employees in recall procedures and considering practice exercises such as mock recalls. FDA explains that these proactive measures, which go beyond the existing guidelines established in Part 7, can help firms assess readiness in anticipation of a potential recall.

Recall Communications Plan. The draft guidance advises firms to establish a recall communications plan (including template communications), that, in the event of a recall, can provide a roadmap to communicating with internal personnel, FDA, customers, and the public. Additionally, firms should understand the applicable regulatory reporting requirements associated with their products (e.g., correction and removal reporting for medical devices).

Product Coding and Distribution Records. Although specific requirements already apply for certain FDA-regulated product categories, FDA recommends that firms implement sufficient product identification coding and maintain product distribution records—whether required or not—to facilitate the timely identification and tracking of products within the scope of a recall. FDA has provided similar recommendations for decades in the Part 7 guidelines (see 21 C.F.R. § 7.59(b)-(c)), but FDA's renewed emphasis on product coding and recordkeeping measures that go beyond those expressly required for specific product categories may prove controversial.

Recall Initiation Procedures. The draft guidance recommends that firms develop and maintain written recall initiation procedures. Such procedures should include specific steps, as appropriate, for stopping sales and distribution of products being recalled, developing a recall strategy, notifying direct accounts about recalled products, providing direct accounts with instructions on how to respond to firm recall communications and dispose of recalled product, and notifying the public about a recalled product that may present a health hazard. The draft guidance also encourages firms to implement various procedures—whether or not required under other provisions (e.g., current good manufacturing practice

[1] 43 Fed. Reg. 26202, 26202 (June 16, 1978) ("[T]he provisions in this final rule are being issued as guidelines . . . and are intended solely to define FDA's recall policy and procedure and to provide guidance to firms so they may more effectively discharged [*sic*] their recall responsibilities.").

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regulations for drugs or the quality system regulation for medical devices)—to identify, investigate, and take action with respect to problems with a distributed product.

Takeaways for Manufacturers and Distributors of FDA-Regulated Products

Manufacturers, distributors, and other entities in the supply chain of FDA-regulated products should review this draft guidance document closely, given that it broadly applies to voluntary recalls of products subject to FDA's jurisdiction. Although broad in applicability, the draft guidance is fairly limited in scope and does not address some of the more complex issues that firms routinely grapple with when considering a potential recall.

For example, the draft guidance does not address the specific considerations for *whether* and *when* a voluntary recall should be initiated. Firms should implement and maintain procedures and train appropriate personnel regarding these critical issues, consistent with the guidelines contained in Part 7, FDA's other recall-related guidance documents, and any statutory or regulatory requirements applicable to the specific product.

The draft guidance also does not provide any recommendations for how firms should perform health hazard assessments ("HHAs") or when it is appropriate to engage third-party expertise to analyze potential safety risks and the likelihood of harm. HHAs help a firm determine, among other things, (i) the appropriate depth of a recall, (ii) whether a public warning regarding the recall is warranted, (iii) the recall classification that FDA will assign, and (iv) for medical devices, whether the recall needs to be reported under 21 C.F.R. Part 806. For guidance on this issue, firms are left trying to apply the principles of FDA's *internal* guidelines on performing HHAs, contained in Chapter 7 of the Regulatory Procedures Manual, but those guidelines can be challenging to adapt to a manufacturer environment.

Despite these limitations, the new draft guidance represents the latest word on FDA's expectations of manufacturers. Firms should evaluate their existing policies and procedures related to recalls to assess whether there are opportunities for improvement based on the draft guidance, such as implementing enhanced training, performing mock recalls, or developing communications templates. Firms should recognize, however, that the new draft guidance does not address some of the most difficult recall-related questions they will encounter.

FDA will be accepting comments on the draft guidance until June 24, 2019. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.

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