How FDA Is Refreshing Its Recall Readiness Guidance

By **Greg Levine, Joshua Oyster and Jessica DeLalio** (May 29, 2019)

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On April 24, 2019, the U.S. Food and Drug Administration released a draft guidance, entitled "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C," to provide additional guidance to industry regarding timely initiation of voluntary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 The draft guidance stresses the importance of being "recall ready" and recommends preparations that manufacturers and distributors should take to facilitate timely voluntary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As described in more detail below, much of the draft guidance echoes the FDA's long-established recall guidelines in 21 C.F.R. Part 7.[1] Although both the draft guidance and the Part 7 guidelines upon which it is based are legally nonbinding, the draft guidance helpfully cross-references related regulations that are mandatory for particular FDA-regulated product categories — e.g., field alert reporting for drugs under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. Section 806.10 and investigating failures and nonconformities for drugs and medical devices under 21 C.F.R. Sections 211.192, 820.100(a)(2). Additionally, the draft guidance provides new recommendations for firms related to training and the development of recall-related standard operating procedures.

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The draft guidance recommends that specific employees be assigned recall-related responsibilities and possess the necessary authority to perform such responsibilities when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. The 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 multilayered distribution chain.

The draft guidance also recommends training the recall-responsible employees in recall procedures and considering practice exercises such as mock recalls. The 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The draft guidance advises firms to establish a recall communications plan — including template communications — that, in the event of a recall, can provide a road map to communicating with internal personnel, the 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, the 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. The FDA has provided similar recommendations for decades in the Part 7 guidelines,[2] but the FDA's renewed emphasis on product coding and record-keeping 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 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 and consider its applicability to their business and products. Even though a draft guidance is subject to change, and even when finalized is not legally binding, in practice it reflects FDA's current thinking and expectations.Some of the recommendations in the draft guidance are new or otherwise framed in a way that may help firms clarify their policies and procedures to improve recall readiness. For example, firms should evaluate their existing policies and procedures related to recalls to assess whether they would benefit from implementing enhanced training, performing mock recalls, or developing communications templates.

Firms should also bear in mind, however, that the draft guidance does not address some of the most challenging issues firms routinely grapple with when considering a potential recall. For example, the draft guidance does not address:

- The criteria by which a firm decides *whether* to initiate a voluntary recall. The FDA's Part 7 guidelines state that a voluntary recall is an effective method for manufacturers and distributors to "carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception *or are otherwise defective*."[3] The FDA also states that a firm's voluntary removal or correction of a violative product will be considered a recall only if the FDA regards the product as involving a violation that is "subject to legal action, e.g., seizure."[4] The FDA distinguishes a recall from a "market withdrawal," which is defined as a firm's removal or correction of a distributed product that involves either "a minor violation that would not be subject to legal action" or no violation.[5] Firms are often unsure whether a recall is warranted

when, for instance, they identify distributed product that violates FDA requirements but judge the associated health risk to be low.

- How to conduct a health hazard assessment, or HHA, that will pass muster with the FDA, and whether firms should engage third-party expertise to provide an outside perspective on potential safety risks and likelihood of harm. The HHA is key to, among other things, determining the depth to which the recall is carried out and the type of effectiveness checking required.

- How to decide when to initiate a recall, as opposed to taking additional time to investigate the source of a product defect or to understand better the likelihood that the product caused or could cause harm. A premature recall can cause unnecessary confusion or even anxiety among health care providers, patients or other consumers, and result in a potentially unwarranted business disruption.

- How to design a call communications plan that will not result in the FDA issuing supplemental or contradictory information. In a guidance document issued this past February entitled "Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C,"[6] the FDA describes criteria for evaluating whether public warnings are needed. Among other things, the FDA states in that guidance that a public warning ordinarily is recommended for "Class I or potential Class I recalls" and some Class II recalls, due to the level of the associated health hazard. But firms must design their initial communications plans well *before* the FDA classifies a recall (and often many months before). Moreover, although the FDA will review a firm's proposed recall strategy, including a proposed communications plan, the FDA is not subject to specific time frames for doing so and routinely reminds firms that "they need not delay initiation of a recall pending [FDA's] review of their recall strategy."[7] Yet, as explained in the guidance regarding public warnings, if a firm issues a public warning that the FDA finds deficient in any respect, the FDA may supplement or correct that warning with its own public warning.

- Whether to notify the FDA of a field action where such reporting is not mandatory. Such decisions can be challenging for a number of reasons, including because the FDA defines the term "recall" to mean a removal or correction of a violative product "against which the agency would initiate legal action, e.g., seizure."[8] A firm cannot know in every case whether the FDA might disagree with a firm's conclusion that a correction or removal is *not* one against which the agency "would initiate legal action." In light of the recent trend toward criticizing firms for "silent recalls," firms might want to err on the conservative side in making such determinations, but each firm must use its own judgment.

Manufacturers and distributors of FDA-regulated products should be familiar with all of the key FDA guidance relating to recalls, including the most recent draft guidance. As the non-

exhaustive list of challenging recall-related questions above shows, however, firms should also have processes, decision-making forms, and internal guidelines in place that anticipate the difficult, yet foreseeable, questions on which the FDA has not provided guidance.

The FDA will be accepting comments on the voluntary recalls draft guidance until June 24, 2019.

Update: This article has been updated to discuss five areas the recent guidance does not discuss that are relevant to manufacturers, distributors and other entities considering potential recalls.

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[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.").

[2] See 21 C.F.R. § 7.59(b)-(c).

[3] 21 C.F.R. § 7.40(a).

[4] 21 C.F.R. § 7.46(a).

[5] 21 C.F.R. § 7.3(j).

[6] https://www.regulations.gov/document?D=FDA-2016-D-3548-0014

[7] 21 C.F.R. § 7.42(a)(2).

[8] 21 C.F.R. § 7.3(g).