

# FDA issues final guidance for public warnings and notification of recalls

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The U.S. Food and Drug Administration (FDA) recently issued a final guidance document regarding the use, content, and circumstances for the issuance of public warnings and public notifications for firm-initiated or FDA-requested recalls, "[Public Warning and Notification of Recalls Under 21 C.F.R. Part 7, Subpart C, Guidance for Industry and FDA Staff](#)" (February 2019). The guidance applies to food, drugs, devices intended for human or animal use, cosmetics and biologics intended for human use, tobacco products intended for human use, and items subject to a quarantine regulation under 21 CFR Part 1240. It does not apply to radiation-emitting electronic products, which are governed only by 21 CFR Parts 1003 and 1004 (to the extent that they are not also regulated as devices).

The purpose of the document is to strengthen and modernize the process for issuing a public warning about a voluntary recall and for notification of recalls. In a [press release](#) dated 7 February 2019, FDA suggests that the guidance document is part of a series of policy steps the agency has taken to better arm consumers with information to protect themselves and their families. The guidance document serves to bridge the gap between a firm's reporting of a recall to FDA and FDA's classification of the recall, by confirming that FDA may issue a public warning or notification (or ask a firm to do so) prior to classifying the recall.

Of note, the guidance states that FDA generally recommends public warnings for recalls that are likely to be or have been classified as Class I recalls, unless specific circumstances indicate that the warning would not be beneficial to the public. The agency also recommends and/or issues warnings for some urgent Class II recalls that, while not rising to Class I hazards, still present a serious hazard to health.

## **When is a public warning appropriate?**

The guidance document provides examples of the circumstances in which a public warning may be appropriate:

- Urgent situations where the recalled product presents a serious risk to health and other means for preventing the use of a recalled product appear to be inadequate. The guidance document provides the following types of device and drug recalls that meet this threshold (among others):

- Urgent recalls of medical devices when retail level consignees cannot identify persons to whom the drug or device was dispensed.
  - Recalls of home-use medical devices that could malfunction and lead to incorrect dosing of drugs or blood volumes.
  - Recalls of sterile injectable drug products that may contain particulate matter.
- A product that has been widely distributed where the end user of the product is not the direct consignee of the manufacturer (e.g., the manufacturer sells product to a wholesaler or distributor that then further distributes to the retail or consumer level) and the actual user cannot be identified, and/or when the manufacturer's recall communications are not effective at reaching the end user. A recent example of this scenario is the numerous public warnings issued by industry and FDA regarding recalls involving alleged carcinogenic impurities in widely distributed pharmaceutical products.

As noted above, public warnings are often appropriate for Class I recalls, unless specific circumstances suggest that it would not be beneficial to the public. Examples of situations where additional public warnings may not be beneficial include where:

- The products have only been distributed to direct accounts and the manufacturer issues a prompt and effective communication.
- The product has only been distributed to the wholesale level and has not been distributed to the customer or retail level.
- There is not enough information to convey risk and appropriate actions for the recipient of the information to follow.
- The product was limited to a small number of consignees, who can be rapidly identified and advised.
- A patient should consult with his or her physician before determining the appropriate action to take (for example, an implanted medical device).

### **Who issues public warnings?**

The guidance document explains that FDA gives firms the first opportunity to prepare and issue public warnings during recalls. FDA indicates that a firm's recall strategy should include a decision by the firm as to whether a public warning is needed and how it should be issued. Firms are encouraged by FDA to include any draft public warning as part of the submission of the recall strategy to the extent that it does not delay strategy development or recall initiation. The guidance notes that, in some cases, firms may choose to issue public warnings without FDA's review; in those situations, the agency may supplement that warning with its own public statement if necessary. When FDA believes that a public warning is appropriate and the recalling firm does not include one in its initial recall strategy, FDA will generally request one from the recalling firm.

The guidance document explains that FDA will generally provide a timeframe for when the firm should issue a public warning and recognizes that timeframes will vary depending on the recall and product. However, firms should generally issue a public warning within 24 hours of the FDA notifying the firm that it believes a public warning is appropriate.

The guidance document also explains that in some situations, FDA may prepare and issue public warnings on its own initiative and in accordance with 21 CFR § 7.42(b)(2). This may occur, for

instance, when the public needs immediate warning concerning a product and the firm has not issued a public warning or a firm's public warning is viewed as being deficient. The guidance document explains that FDA will ordinarily work with the recalling firm to ensure the factual accuracy of the agency's own public warning but is not required to contact the firm before issuing a public warning or allow the firm to review the agency's proposed statement.

### **What should be included in a public warning?**

The guidance document provides that the following elements should be included in a public warning that is intended to alert the public that a product being recalled presents a serious hazard to health:

- Information to help identify the recalled product, including pictures and numerical information.
- Geographic area and dates of distribution of the affected product.
- A thorough description of the product effect, health hazard, and reason for recall.
- Name and contact information for the recalling firm.
- Instructions for users of the product.
- Number and nature of any complaints, illnesses, or injuries reported for the product and related to the defect necessitating the recall.
- A description of common symptoms of any illness of concern.
- If appropriate, information on the recalling firm's supply chain relationships (i.e., any wholesaler or retailer to whom the product was sold).

In addition, the headline of the public warning should include the brand name, type of product, and the hazard promoting the recall, with the guidance providing a sample format.

FDA recommends not including the following information in a public warning:

- Content that detracts from or defeats the purpose of the warning.
- Messages that cloud or lengthen a warning, thereby distracting a recipient.
- Any promotional information about the firm or the firm's products.
- Wording that can be seen as minimizing the hazard.

FDA may find a warning deficient if it does not contain the information listed above or if FDA determines the message did not reach the target audience. This can include failure to provide a translation if the product is likely to be used by a non-English speaking population. Any unverifiable factual information may also result in FDA issuing its own public warning. FDA also encourages firms to monitor media coverage and take further action to raise public awareness if media coverage appears to be insufficient. FDA may issue its own public warning or supplement a company's public warning in situations where a company refuses to issue a public warning after FDA has recommended one, an ongoing recall is not prompt or effective, or where new adverse events are reported after a recall has been completed.

## How is a public warning distributed and displayed?

The guidance document provides that public warnings can be distributed by press releases on both general and specialized news media and/or media outlets, sending emails to a mailing list or subscription service, posting on the FDA and company website, and/or using social media. The distribution of the press release, if not widespread, should be disseminated within the geography where the product was distributed, if the company can be certain that distribution was limited to certain geographies.

The guidance emphasizes the criticality of distributing public warnings in a way that the information conveyed in the warning actually reaches the affected public. This may include the use of nontraditional pathways for information dissemination. For example, if a product is available online or distributed nationally, the public warning should also be available online and/or distributed nationwide. Ultimately, the firm should utilize a pathway to ensure that the information is distributed in a manner designed to reach its target audience.

A firm displaying a public warning on its own website should assure that it is prominent and accessible from both its home page and a web search. It should remain publicly accessible until the product is no longer expected to be used.

FDA facilitates dissemination of certain recalls and warnings using [FDA.gov/Recalls](https://www.fda.gov/recalls) and [FDA.gov/MajorProductRecalls](https://www.fda.gov/majorproductrecalls) (these websites are further discussed in the guidance document). The guidance document also reminds firms that FDA provides public access to information on recalls (regardless of the level of hazard) by posting a listing of recalls according to their classification (Class I, II, or III) in the [FDA Enforcement Report](#).

## How can Hogan Lovells help?

The newly published guidance articulates many of the agency's practices we have observed over the years related to device and drug recalls and public notification. The guidance helpfully explains more of the agency's rationale behind its practices, which is always a benefit to industry. In particular, as it relates to medical device and drug recalls, the guidance will help manufacturers work through complex decisions and planning around how to best mitigate and communicate the potential for serious risk.

Where device and drug recalls present the potential for serious adverse consequences or death, the analysis of how to address the issue in the field and how best to reach affected patients or consumers can be extremely complicated as companies work to effectively mitigate the risk while minimizing unintended consequences linked to how they communicate the information. For example, where a medical device is already implanted in a patient and a company identifies the potential for a catastrophic failure that occurs at a very low rate, a broad communication that reaches all patients (who may or may not be at risk for the failure) may well create more anxiety and confusion than a more targeted communication to certain affected patients through their health care provider.

Even worse, where the investigation for the same issue is not yet far enough along or complete such that the company is not able to fully describe the failure, identify the root cause or quantify the risks, and/or make meaningful recommendations to mitigate the risks, the incomplete information may have a negative impact on the ability of health care professionals and patients to make decisions together. Because of the benefits provided by certain medical devices and the large population of devices that are implanted, perform critical functions, or are life-sustaining, simply removing the product may not be a viable option for mitigating risk. Thus, a company's desire and willingness to communicate issues quickly to customers should be balanced against the impact that communication may have on patient care.

This guidance shows that the agency is open to working with manufacturers to find the most effective way to communicate recalls that have the potential for serious health consequences to patients and health care providers, even in situations where the agency has classified a recall as Class I and is inclined to apply its policy on requiring press releases to be issued within 24 hours of classifying the recall. As companies work through these difficult issues, they should take comfort that FDA is open to considering situations where such a notification may not be helpful or may be counterproductive to the mutual goal of protecting the public health.

Further, the guidance makes clear that FDA is willing to consider other approaches to reaching users based on the facts and circumstances of the recall, which means manufacturers should consider whether public notification is warranted and be prepared to present alternatives if it believes there are approaches that will more effectively reach consignees knowing the agency is willing to give the company's strategy and rationale fair consideration.

Our Medical Device and Pharmaceutical and Biotechnology practices have decades of experience working with clients and FDA in developing and executing successful recall strategies (domestic and global) that take into consideration the uniqueness of every situation, the risks presented by the issue, the market in which the product is sold, the patient population that is affected, and the agency's likely reaction to how the company is approaching the recall.

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