Urgent, Urgent, Urgent … Emergency:FDA Advises Companies to Issue Appropriate Product Recall Warnings

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Channeling the rock band Foreigner and its 1981 hit, "Urgent" (or the Beatles' "Get Back" single), the Food and Drug Administration issued a draft guidance in January 2018, cautioning industry to properly warn the public about product recalls … or else.[1] This draft guidance was issued one month after a report from the Office of Inspector General for Department of Health and Human Services (OIG) on FDA's food recall process, which found deficiencies in FDA's oversight of recall initiation and monitoring.[2] While the draft guidance is not legally binding, it reflects the agency's current thinking and is worth reviewing. This Bulletin will highlight FDA's recommendations and offer AGG observations.

Summary

- Although this draft guidance was issued soon after OIG's food recall report, the guidance applies to almost all FDA-regulated products[3]
- Generally, a company should issue a warning to the public within 24 hours of an agency request to do so
- If a company fails to do so, FDA may issue its own public warning
- FDA may add to a company's warning if the agency considers it inadequate
- The agency notes that public warnings are for urgent situations where a product being recalled presents serious health hazards, and other methods to prevent the use of the recalled product will not suffice
    - (e.g., when retailers cannot identify the recipients of drugs they dispensed)
    - typically recommended for Class I recalls (i.e., reasonable probability that use/exposure will cause serious adverse health consequences or death)
        - FDA may also recommend public warnings with some urgent Class II recalls (e.g., use/exposure may cause temporary or medically reversible adverse health consequences, remote probability of serious adverse health consequences)
- A company might not be required to utilize a public warning if it can prevent use of the product at the outset
    - when a company has records showing exactly where a product has gone, telephoning direct accounts, such as wholesalers, before they distribute or sell the products, may be adequate to prevent use of the product
    - letters or emails may not be sufficient due to delays and lack of confirmation receipt
    - if there are so few users that all can be contacted directly, there might not be a need for a public warning
- A company should prepare a strategy for recalls it initiates, and that strategy should include whether and how to issue public warnings
    - while FDA typically reviews and comments on recall strategies, the agency does not require firms to delay recalls while it reviews the strategies

1 See Public Waring and Notification of Recalls Under 21 CFR Part 7, Subject C: Draft Guidance for Industry and FDA Staff," www.fda.gov/downloads/safety/recalls/industryguidance/ucm592851.pdf.

2 Report in Brief available at https://oig.hhs.gov/oas/reports/region1/11601502RIB.pdf.

3 The draft guidance "does not apply to radiation emitting electronics which are governed by 21 CFR Part 1003 and 1004." See https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf.

- Public warnings should include the following:
  - information such as images, product identification numbers, packaging information or brand names that help people identify the recalled product
  - geographic areas and dates of distribution
  - details regarding the product defect, health hazard and reason for the recall
  - name and contact information of the recalling firm
  - instructions to consumers
  - the number and nature of any illness, injuries or complaints associated with the product
  - description of the common symptoms of any illness or concern
- FDA recommends that public warnings not include:
  - lengthy warnings with distracting messages
  - content that detracts from or defeats the purpose of the warning
  - promotion of the qualities of the recalled product or other company products
  - statements that the company is conducting the recall out of "an abundance of caution" when illness or injury have resulted or when pathogens have been found in the product
- FDA may consider a public warning deficient if it does not adequately identify the recalled product and associated risk, fails to reach a target audience (such as a particular region or a Spanish-speaking community), or contains factual statements that FDA cannot confirm
- FDA recommends that companies match press release distribution about public warnings to affected communities
  - e.g., if a product is available online or distributed nationally, the warning should be available online and/or distributed nationally
  - for products used mainly in regional markets or by non-English speakers, there should be warnings targeting those regions or communities and written in the appropriate language
- Industry may submit comments to the draft guidance by March 20, 2018

AGG Observations

- Take product recall communications seriously
  - don't use as a promotional opportunity
  - be specific, factual, and simple
- Be proactive in planning for public recall communication with strategy development, appropriate personnel involvement, and adequate timing
- Consider involving FDA in the notification process at the outset
  - while there can be a reluctance to have FDA micromanage the process or to request more than the company might want to disclose, an inadequate notification will make things worse with the agency
- Evaluate whether a public notice is necessary
  - don't be too aggressive or cavalier, but a particular set of facts may alleviate the need, so long as the public health risk is proactively addressed

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