Understanding FDA Drug Recall Procedures

It is important to pay attention when a product is recalled, but with all the different sources of information, and the different types of recalls, it can be confusing. Recalls, designed to protect the public's health, are used as a way to deliver information to consumers in an expeditious manner.

A recall is an action taken by a manufacturer to remove a product (food, drugs, medical devices and cosmetics) from the market, initiated either by the manufacturer or by request from the FDA. In either case, the manufacturer removes or corrects a product that is in the market and in violation of FDA rules and regulations. In both cases, the FDA considers the recall to be manufacturer initiated.

Alternatively, an FDA-mandated recall, also known as a mandatory recall, occurs when the FDA orders a manufacturer to recall a product or mandates recall requirements. The FDA's role is to oversee the manufacturer's recall strategy, monitor the recall for effectiveness and classify the recall.

Here are the different recall classifications:

- **Class I:** Includes a health hazard situation where there is reasonable probability that the use of the product will lead to serious, adverse health consequences or death.
- **Class II:** Includes a potential health hazard situation in which use of or exposure to a violative product may cause temporary or medically-reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III:** Includes a situation in which use of or exposure to the product is not likely to cause adverse health consequences.
- **Market withdrawal:** When a product has a minor violation that would not be subject to FDA legal action a "market withdrawal" occurs. The product is removed by the firm from the market or corrects the violation.

### Medical device safety alert: Released in circumstances where a medical device may present an unreasonable risk of substantial harm. These situations also are considered recalls in certain cases.

A recall named voluntary, requested and mandatory depends on who initiates the process. Based upon the gravity of the situation, the FDA will issue a public warning.

#### Voluntary Recall: Initiation of a Recall by a Manufacturer

Consistent with its responsibility to protect the public health from products that are defective or potentially harmful, a manufacturer may voluntarily initiate a recall. If a recall is manufacturer-initiated, the FDA reviews the information provided by the manufacturer, conducts a health hazard evaluation, classifies the recall, and then advises the manufacturer in writing of the assigned recall classification.

The FDA then places the notice of the recall in the FDA Weekly Enforcement Report. Nearly all recalls implemented in the U.S. are begun on a voluntary basis by the manufacturer.

If a manufacturer has voluntarily initiated a recall, it is the manufacturer's responsibility to promptly notify each of its direct accounts. If the recall extends beyond direct accounts, then the direct accounts should be instructed by the recalling manufacturer to contact sub-accounts that may have received the product. Once all accounts have been informed about the recall, they must promptly follow the recall strategy that was previously put in place for that account.

#### FDA Requested Recall

In urgent situations, the FDA may request a recall. The request is directed to the manufacturer that has the primary responsibility for making or marketing the product. Class I category recalls are most often requested recalls. It is important to note the FDA considers an FDA requested recall to be manufacturer initiated.

The Associate Commissioner for Regulatory Affairs approves all recall requests from the FDA. A letter outlining the need for a recall is sent to the manufacturer. After a recall has begun, the recall is entered in the Recall Enterprise System. The RES is a database used by the FDA to submit, update, classify and terminate recalls.

#### FDA Mandated Recalls

The FDA’s authority to issue a mandatory recall is very limited. Subjects of mandatory recalls can include devices, biological products, human tissue intended for transplantation, infant formula, tobacco products and food. The FDA also has discretion to order a mandatory recall if it finds that a human cell, tissue or cellular or tissue-based product is a source of dangerous infection to humans or does not adequately protect against communicable disease.

### Elements of a Recall

Each recall follows specific timelines and procedures depending upon the circumstances. For example, each recall is initiated with a written order that states the violation, the product, lot and serial numbers to be recalled, and the timeline for the recall. Each recall is unique and requires its own recall strategy developed by the Center Recall Unit. The CRU will consider how far the recall should extend, whether the public needs to be warned and if so, in what geographical area, and the appropriate assessment for recall effectiveness.

### Recalls Can Be Issued By:

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<thead>
<tr>
<th>VOLUNTARY</th>
<th>FDA REQUESTED</th>
<th>FDA MANDATED</th>
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<tbody>
<tr>
<td>Almost all recalls are begun as voluntary</td>
<td>Initiated by manufacturer</td>
<td>Narrowly restricted by federal statute</td>
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<td>Manufacturer is responsible for contacting users about recall</td>
<td>FDA due to potential harm</td>
<td>FDA can only order recall if it fits within statute limitation</td>
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<td>Based on agency determination that action is needed to protect public health and welfare</td>
<td>FDA may issue public warning</td>
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**VOLUNTARY & FDA REQUESTED RECALLS ARE CONSIDERED MANUFACTURER INITIATED**

All recalls are initiated with a written order citing violation, product, lot and serial numbers and timeline for recall.