U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Drugs

Questions and Answers on Current Good Manufacturing Practices, Good Guidance Practices, Level 2 Guidance Holding and Distribution

Human Drug Recalls

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1. What is a recall?

Recalls are actions taken by a firm to remove from the market any product that is in violation of laws administered by the FDA. Recalls of a drug may be conducted on a firm's own initiative or by FDA request.

A recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products [see 21 CFR 7.40(a)]. Under the FDA's Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals, manufacturers must establish and follow written procedures to facilitate the recall of defective products from the market [see 21 CFR 211.150(b)].

2. Can FDA mandate a recall of human drugs?

FDA does not have authority to mandate a recall of a human drug, but it can take more authoritative legal actions against manufacturers that persist in marketing a defective product, such as seizure and injunction.

A recall is a firm's removal or correction of marketed product that FDA considers to be in violation of the laws it administers, and against which FDA would otherwise initiate more powerful legal action [see 21 CFR 7.40(c); also see FDA Investigations Operations Manual, Chapter 7- *Recalls*, section 7.1.1.1, available at: http://www.fda.gov/ICECI/Inspections/IOM/ucm122545.htm[1]]. Thus, manufacturers typically initiate voluntary recalls when a defect is found within a marketed batch to avoid a potentially more significant enforcement action by FDA.

3. Are OTC drugs subject to the same recall provisions as prescription drugs?

Yes, FDA's recall expectations for drugs apply equally to OTC and prescription. The CGMP regulations also apply to all drug products, whether OTC or prescription (see Compliance Policy Guide 450.100, CGMP Enforcement Policy - OTC vs. Rx Drugs, available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074387.htm[2].

4. Do manufacturers of OTC products have to report quality defects?

Manufacturers of OTC drugs approved in a new drug application are required to report quality defects (see 21 CFR 314.81). Manufacturers or distributors of OTC monograph drugs (these are drugs that are not approved in a product-specific application), are not required to submit quality defect reports. However, the manufacturer, packer, or distributor whose name appears on the label of an OTC drug without an approved application (i.e., OTC monograph drugs) must submit to FDA any report received of a serious adverse event associated with such drug when used in the United States (see section 760 of the Act). Thus, if a serious adverse event is caused by a quality defect, FDA will receive a report about the event (see also Guidance for Industry, "Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application[3]"

5. Does FDA expect firms to investigate both released and rejected lots for potential recalls?

Yes. Under 21 CFR 211.180(e), manufacturers must establish and follow written procedures for periodically reviewing complaints, recalls, returned or salvaged drug products, and investigations of product discrepancies. Firms must also review an appropriate number of batches, whether approved or rejected, and, where applicable, records associated with the batches, to ensure that all potentially affected product is thoroughly investigated and appropriate follow-up action is taken [21 CFR 211.192].

6. What happens if a firm does not voluntarily recall a defective product?

FDA expects that a firm will voluntarily recall a drug that is defective or flawed if it could be hazardous to health. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the FDA, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing [21 CFR 7.40(c)].

References:

- Code of Federal Regulations (CFR) Title 21 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm[4]

Contact for further information:
Division of Manufacturing and Product Quality (HFD-320): CGMP Subject Contacts
http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm096102.htm[5]

Related Information

- Questions and Answers on Current Good Manufacturing Practices (cGMP) for Drugs[6]

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