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FDA Issues Initiation of Voluntary Recall Draft Guidance

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- Today, FDA published a draft guidance on ways to prepare, plan, and work with the FDA to ensure voluntary recalls are initiated properly and timely. The draft guidance, titled "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C," applies to voluntary recalls of all products subject to FDA's jurisdiction, including food, drug, and devices intended for human or animal use, any cosmetic and biological product intended for human use, any tobacco product intended for human use, and any item subject to a quarantine under 21 CFR Part 1240.
- As mentioned in FDA's press release, the draft guidance includes recommendations in three key areas:
    - Training – The draft guidance emphasizes the importance for firms in a product distribution chain to be "recall ready" to help minimize public exposure to products that are in violation of the Food, Drug, & Cosmetic Act and other laws administered by FDA. The draft guidance advises companies on ways to best identify and train appropriate personnel on their responsibilities during a recall, establish a recall communications plan, and identify what FDA reporting requirements there may be, among other things.
    - Recordkeeping – The draft guidance discusses the need for thorough and organized distribution records, that should be maintained over a period of time. Further, the FDA states that products should have specific product coding, whether required by law or not. Product coding assists in facilitating effective recalls and may help a recalling firm accurately define and limit the scope of the recall effort.
    - Procedures – The draft guidance recommends that firms consider preparing and maintaining written recall initiation procedures to help minimize delays, ensure that necessary actions are not overlooked, and minimize the disruptive effect a recall can have on a business. FDA notes in the draft guidance that recall initiation procedures do not supersede any other specific recall plan requirements (e.g., HARPC written recall plans).
- FDA believes the draft guidance effectuates an important step towards achieving the Agency's goal of quickly executing recalls and reaching consumers with timely information to limit the impact of potentially dangerous products. Stakeholders may submit comments on the voluntary recall draft guidance until June 24, 2019.

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