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Device-Makers Can Be 'Recall Ready' With This Step-By-Step Guidance From FDA

by Shawn M. Schmitt

From general preparations to the development of correction and removal initiation procedures, the US agency is offering recommendations to firms on how to recall a problem product. In its new draft guidance, the FDA says it's "critical" for manufacturers to be "recall ready."

The US FDA is offering device-makers step-by-step guidance on how to recall a problem product, from general preparations to the development of correction and removal initiation procedures – and much more.

The agency, through its Office of Regulatory Affairs, gives the advice in an April 24 *draft guidance document*, "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C," which says it's "critical" for firms to be "recall ready."

"For a recall to be effective and timely, it's crucial that companies be prepared in advance to take all necessary steps for when a recall is initiated," FDA Associate Commissioner for Regulatory Affairs Melinda Plaisier said in an April 23 *statement*.

When finalized, she said the guidance will "provide industry with clear information on ways to prepare, plan and work with the FDA to ensure voluntary recalls are initiated properly and promptly."

Prepping For A Recall

The draft guidance directs manufacturers to prepare for a recall by taking specific steps, including identifying "appropriate personnel" to handle "recall-related responsibilities." It notes that a company should also identify alternate employees who can stand in if needed.

Further, the document says firms should establish a "recall team" if it "anticipates that its recall efforts would be complex or have other complicating factors," such as having "a large or

multilayered distribution chain."

The FDA notes that a "recall team could include a designated recall coordinator, and an official or employee with decision-making authority to initiate a product recall." (Also see "*'SWAT Teams' Recommended For Device Firms As They Handle Product Recalls*" - Medtech Insight, 16 Jul, 2014.)

Employee training and conducting mock recalls is also suggested by the agency in its draft guidance.

"Proper training of personnel is perhaps one of the most important elements to effectively executing a recall," the FDA's Plaisier said.

The draft guidance also urges firms to establish a recall communications plan. "Such a plan should address internal communications, communications with FDA, and communications to direct accounts or the public in the event that a recall is deemed necessary," the document says. "The firm should consider identifying specific points-of-contact ahead of time and should maintain draft templates that help it issue recall communications promptly," such as notification letters and draft press releases.

> *"Thorough and organized recordkeeping is especially important." – Melinda Plaisier*

The FDA also recommends that companies ensure they're using Unique Device Identifiers (UDIs) on their products and identify regulatory reporting requirements associated with their devices. (Also see "*When A Recall Hits, Embrace Your Regulator For The Common Good: Patient Safety*" - Medtech Insight, 30 Mar, 2018.)

Maintaining distribution records is also important, the agency says. "Distribution records should include enough detail to identify the consignees that actually received the recalled product and must conform with any applicable requirements," the guidance notes. And "direct accounts that further distribute the product should also maintain records of their consignees that actually received the product, to ensure that the recalling firm's instructions are extended to all consignees in the distribution chain."

"Thorough and organized recordkeeping is especially important as the agency continues its

efforts to improve recalls through product traceability by tapping into modern approaches such as *blockchain* technology to further our mission of protecting public health," Plaisier said.

Recall Initiation Procedures

The agency through its draft guidance also recommends that device-makers prepare and maintain written recall initiation procedures.

Such procedures "help to minimize delays created by uncertainty as to the appropriate actions to take when a decision is made to initiate a recall, help ensure that necessary actions are not overlooked, and may minimize the disruptive effect a recall can have on a firm's business," the guidance states.

It says the procedures should "assign responsibility and describe the steps to perform all actions related to initiating a recall," including:

- Ceasing distribution, shipment and/or sales of affected product(s);
- Developing a recall strategy;
- Notifying direct accounts about the product being recalled, including what should be done with the recalled product; and
- Notifying the public about a product that presents a health hazard, when appropriate.

"Using initiation procedures can help reduce the amount of time a defective or potentially harmful product is on the market, and that in turn reduces the potential exposure to consumers," Plaisier said.

"These procedures should clearly describe the appropriate actions to take when a decision is made to initiate a recall," she added. "They should also help ensure that necessary actions are not overlooked and may minimize the disruptive effect a recall can have on a company's operations."

Other Important Steps

The draft guidance goes on to say that if a company identifies trouble with a device, it should identify and investigate the problem.

Firms should also "make decisions and take action" as needed, and consult with the agency by *contacting an FDA recall coordinator*.

"Recall coordinators provide a recalling firm with information about the recall process and are

available to work closely with the firm throughout the course of the recall," the guidance says.

The document notes that while domestic recalling firms should contact a division recall coordinator, foreign manufacturers should interact with ORA directly.

> *The FDA considers a company's first communication of any type about a recall to be the date of that recall's initiation.*

The guidance also recommends that device-makers "should initiate a voluntary recall by promptly sending recall communications to each affected direct account, and by issuing a press release or other public notice, if appropriate."

It says the agency considers a company's first communication of any type about a recall to be the date of that recall's initiation.

Further, "a recalling firm should clearly identify the level in the distribution chain to which the recall is to extend, and should provide instructions to direct accounts to extend the recall to their consignees if the product could have been further distributed."

The draft guidance closes with this warning to manufacturers: "In the event that a recalling firm's actions do not adequately protect the public from a violative product, ie, the firm fails to initiate a recall effectively, FDA may consider taking other appropriate regulatory actions."

Stakeholders can comment on the draft through 23 June at *Regulations.gov* under docket No. FDA-2018-D-2074.