Medical Device Recalls and Reports of Corrections and Removals, Part 7, Part 806: Frequently Asked Questions

Introduction

General information regarding recalls, including removals and corrections, is available on the Industry Guidance for Recalls webpage: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls. This resource links to guidances for Industry and Staff about the recall process, a listing of Office of Medical Device and Radiological Health and Office of Biological Products Operations recall coordinators, the geographic boundaries for each recall division, model letters, response forms, and training modules.

FAQs: Questions and Answers

This section is intended to answer common questions about medical device recalls and reports of medical device corrections and removals. This FAQ does not address reports submitted as a requirement of the Electronic Product Radiation Control Program (EPRC).

Q: In what format should we submit our lists of consignee information?

A: Manufacturers or importers are required to include in their reports of corrections and removals the names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee. 21 CFR 806.10(c)(11). It is recommended that you submit this information in a sortable electronic format, such as a spreadsheet with the names, addresses and telephone numbers for the consignees. When feasible, you should include other relevant fields in the spreadsheet that might help facilitate follow-up by FDA (e.g., lot numbers, shipment dates).[1]

Q: How do I submit the Unique Device Identifier (UDI)?

A: Manufacturers or importers are required to include in their reports of corrections and removals the Unique Device Identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. 21 CFR 806.10(c)(5). We recommend the following format for submitting this information:

1. If you are providing only UDI-DI, submit as "UDI-DI:" and the number.
2. If you are providing full UDI, submit as "UDI:" and the number with all parentheses and special characters as provided. DO NOT include any blank spaces between characters within each UDI.
3. If the recall impacts multiple models, then group UDI information by model. For example:

Product 1: (providing UDI-DI only)

[1] For additional information about what to include in a report of correction or removal, see 21 CFR 806.10(c); Product Recalls, Including Removals and Corrections (March 2020); CDRH Learn Recall module: https://www.fda.gov/files/medical%20devices/published/CDRHLearn--Recall-Module-21-CFR-Part-806--Medical-Devices--Reports-of-Corrections-and-Removals.pdf; CDRH Learn: Medical Device Recall videos and webinars, e.g.: Medical Device Recalls: Guidance for Industry (yorkcast.com).

UDI-DI: 00123456789012, Model A, Lot A213A1, Lot A213A2, Lot A213A3
UDI-DI: 00123456789013, Model B, Lot A213B1, Lot A213B2
UDI-DI: 00123456789014, Model C, Lot A213C1.

Product 2: (providing full UDIs)
UDI: (01)00123456789012(11)141231(17)150707(10)A213A1(21)1234, Model A, Lot A213A1
UDI: (01)00123456789012(11)141231(17)150707(10)A213A2(21)1235, Model A, Lot A213A2
UDI: (01)00123456789012(11)141231(17)150707(10)A213A3(21)1236, Model A, Lot A213A3
UDI: (01)00123456789013(11)141231(17)150707(10)A214B1(21)1236, Model B, Lot A213B1
UDI: (01)00123456789013(11)141231(17)150707(10)A214B2(21)1236, Model B, Lot A213B2
UDI: (01)00123456789014(11)141231(17)150707(10)A213C1(21)1236, Model C, Lot A213C1.

Long lists of impacted UDIs may be submitted as an Excel file, with separate columns for each data element you provide, grouped by UDI-DI as suggested above.

Q: Should I also submit labeling information?

A: FDA recommends that you include labeling, which includes the individual package label and the directions for use, in your reports of corrections and removals.

Q: I have conducted a recall, should I also conduct an effectiveness check?

A: FDA recommends that you consider effectiveness checks for every recall. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the firm's recall strategy have received notification about the recall and have taken appropriate action (21 CFR 7.42(b)(3)).

Q: What are some methods to conduct recall effectiveness checks?

A: In conducting a recall effectiveness check, there are certain basic questions that consignees should be asked. The purpose of these questions is to determine whether the recall notification was received, the product involved was handled as instructed in the recall notification (including whether the product was returned or corrected, including whether corrected *in situ* by reprogramming or upgrading software), the product was further distributed by the consignee before receipt of the recall notification, and if so, were these additional consignees notified. Other questions may need to be asked depending upon the nature of the recall.

The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. Responses from consignees should be logged. Please note, "read receipts" indicating that an email containing a recall notification was opened or viewed, or certified delivery receipts indicating that a letter containing a recall notification was delivered, would not serve as confirmation that consignees have taken appropriate action in response to the recall notification.[2]

[2] Your effectiveness check is a means of evaluating the effectiveness of your recall. If your effectiveness checks indicate that the recall communication was not received and/or its instructions were not followed, then you should take steps to make the recall effective. These steps may involve using alternative means of contacting your customers or sending out a follow up communication that better identifies the product, better explains the problem and/or provides better instructions to the consignees.

When the last of the recall effectiveness checks have been made, a final tabulation of the results of the contacts and questionnaires should be made. Evaluation of this data and the results of the recall should give an estimate of the effectiveness of the recall.

For more information about effectiveness checks, see 21 CFR 7.42(b)(3), the Methods for Conducting Recall Effectiveness Checks guide referred to in 21 CFR 7.42(b)(3),[3] and section IV.1. of FDA's Product Recalls, Including Removals and Corrections Guidance for Industry.

Q: How will my recall be evaluated?

A: You will be asked to provide Recall Status Reports to your FDA Division Recall Coordinator (DRC) after initiating a recall (usually on a monthly basis but more frequently when indicated). Your Recall Status Reports should usually include the following information: dates and method of customer notification; number of customers notified; number of customers that responded; quantity of recalled product returned or otherwise accounted for; number of customers that did not respond (FDA may ask for the identity of such customers); estimated time frame for completion of the recall; and details of your recall effectiveness checks. Because it is important to attempt to establish the root cause of a problem that results in a product recall so that appropriate corrective actions can be taken, we recommend that you also provide the root cause information to your DRC or appropriate Center contact. In addition, we also recommend that you explain to your DRC or appropriate Center contact, the corrective actions taken to prevent recurrence.[4]

Q: What should I submit to request termination of my recall?

A: A recall will be terminated when FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product (see 21 CFR 7.55(a)). A recalling firm may request termination of its recall by submitting a written request stating that its recall is effective in accordance with the criteria set forth in 21 CFR 7.55(a), and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product (see 21 CFR 7.55(b)).

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[3] Methods for Conducting Recall Effectiveness Checks is available upon request from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[4] The Quality Management System Regulation requires that each manufacturer takes action to eliminate the causes of nonconformities in order to prevent recurrence, with corrective actions taken without undue delay and in a manner proportionate to the effects of the nonconformities encountered. The manufacturer must document a procedure for: reviewing nonconformities (including complaints); determining the causes of nonconformities; evaluating the need for action to ensure that nonconformities do not recur; planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; and reviewing the effectiveness of the corrective action taken. Records of the results of any investigation and of action taken shall be maintained. (21 CFR 820, ISO13485:2016 Clause 8.5.2).