Convenience Kit Reporting Requirements for Corrections, Removals, and Recalls, or Adverse Events

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.

For general information regarding how to report medical device problems, see the FDA's webpage on Medical Device Reporting (MDR): https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems. This resource contains links to guidances for Industry and Staff about reporting requirements, instructions for mandatory reporting, and where to search for medical device reports.

FAQs: Questions and Answers

This FAQ is intended to answer common questions regarding the method by which convenience kit manufacturers are to report corrections or removals under 21 CFR Part 806 (Medical Devices; Reports of Corrections and Removals) and to report adverse events under 21 CFR Part 803 (Medical Device Reporting). This FAQ does not address reports submitted as a requirement of the Electronic Product Radiation Control Program (EPRC).

Q1: What is a convenience kit?

A: A convenience kit refers to when two or more different medical devices are packaged together for the convenience of the user.[1]

Q2: Are convenience kits medical devices subject to 21 CFR Part 806?

A: Yes. Convenience kits are devices as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act) at section 201(h)(1) and are subject to the requirements at Part 806.[2]

Q3: Who is considered a manufacturer or importer of a convenience kit?

A: Assemblers of convenience kits are considered "manufacturers," which means "any person who manufacturers, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures,"[3] including any person who, "…

[1] 21 CFR 801.3.
[2] *See* 21 CFR 806.1 and preamble, 78 FR 58786 (Unique Device Identification System Final Rule, September 24, 2013).
[3] 21 CFR 806.2(h).

[r]epackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer."[4] Part 803 also considers U.S. agents of foreign manufacturers to be manufacturers.[5] Likewise, "importers" of convenience kits are subject to the requirements at Part 806.[6]

Q4: Must a manufacturer or importer submit a Part 806 report for a correction or removal?

A: A medical device correction or removal must be reported by manufacturers or importers to the FDA under Part 806 if the action was initiated to reduce a risk to health or remedy a violation caused by the device which may present a risk to health absent other circumstances.[7] A risk to health means: (1) a reasonable probability that use of or exposure to the product will cause serious adverse health consequences or death; or (2) that use of or exposure to the product may cause temporary or medically reversible adverse health consequences or an outcome where the probability of serious adverse health consequences is remote.[8]

A required Part 806 report must be submitted to FDA within 10 working days from the time the firm initiates the correction or removal, including recall, in accordance with 21 CFR 806.10(b).[9]

Q5: Is the manufacturer of a convenience kit required to submit a report of correction or removal under Part 806 even if the manufacturer of a finished device component within the kit has not yet initiated a correction or removal?

A: Yes. Medical device convenience kit manufacturers or importers are required to comply with all general controls, such as manufacturing, labeling controls, and post-market reporting of adverse events, or any corrections and removals of product that were initiated to reduce a risk to health or remedy a violation of the FD&C Act caused by the device which may present a risk to health, absent certain circumstances.[10] Convenience kit manufacturers must report such corrections or removals of kits containing finished device components within 10 working days of initiating the correction or removal, even if that correction or removal is prior to the finished device component manufacturer's notification.[11]

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[4] 21 CFR 806.2(h)(1).
[5] 21 CFR 803.3(l).
[6] *See* definition of "importer" at section 803.3(j) and section 806.2(g).
[7] 21 CFR 806.10(a).
[8] 21 CFR 806.2(k).
[9] *See also* Guidance for Industry and FDA Staff, Distinguishing Medical Device Recalls from Medical Device Enhancements, October 15, 2014.
[10] FD&C Act § 513(a)(1)(A)(i). *See also* 21 CFR 806.10(a).
[11] 21 CFR 806.10(a) and (b). *See also* Final Guidance for Industry, Sterilized Convenience Kits for Clinical and Surgical Use, January 7, 2002.

Q6: What if the manufacturer of a finished device component contained within a convenience kit has already reported a removal or correction of that finished device component under 21 CFR 806.10? Is the convenience kit manufacturer also required to submit a report?

A: Yes. Manufacturers or importers of convenience kits who initiate a correction or removal to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device which may present a risk to health, as described in 21 CFR 806.10(a), are required to submit a written report to FDA. A convenience kit is "two or more different medical devices packaged together for the convenience of the user."[12] FDA has interpreted this to mean a a device that contains two or more different medical devices packaged together and intended to remain packaged together and not to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before being used by an end user.[13] Therefore, if one device in a convenience kit is subject to a correction or removal under Part 806, then the convenience kit is also subject to a separate correction or removal, requiring the manufacturer or importer of the convenience kit to submit its own report under Part 806 within 10 working days of its own initiation of the correction or removal.[14]

Additionally, manufacturers of a finished device component who have reported a correction or removal of that finished device component under Part 806, and have sent a recall communication in accordance with Part 7 to the manufacturer or importer of a convenience kit containing that part as a consignee, shall make the convenience kit manufacturer aware of the correction or removal action, which puts the manufacturer or importer of the convenience kit on notice of its own correction or removal obligations.[15] As described in FDA guidance,[16] a firm's written procedures for initiating a recall and performing actions related to initiating a recall should assign responsibility and describe the steps to perform all actions as appropriate to the firm or facility, including procedures for notifying direct accounts about the product being recalled, and what should be done with respect to the recalled product. The recipients of a recall communication, i.e., a notified direct account or consignee, should implement their own recall initiation procedures to extend the recall promptly to its direct accounts that may have received the affected product, in accordance with the instructions received from the recalling firm.[17] Convenience kit manufacturers are required to maintain records of their finished medical devices[18] and therefore are likely better positioned to verify the effectiveness of a correction or

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[12] 21 CFR 801.3.
[13] *See* Guidance for Industry and Food and Drug Administration Staff, Unique Device Identification: Convenience Kits, April 26, 2019.
[14] 21 CFR 806.10(a) and (b).
[15] *See* 21 CFR 7.49; 806.10(a), (c)(11) and (12).
[16] *See* Guidance for Industry and FDA Staff, Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, March 2022.
[17] 21 CFR 7.49(d). *See also* Guidance for Industry and FDA Staff, Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, March 2022.
[18] *See* 21 CFR Part 820 generally.

removal of a kit containing a finished device component than the original manufacturer of that finished device component.

Reports under Part 806 have an intrinsic value in that they help us fulfill our mission to alert the public to potential dangers of medical products provided to them and to remove those products from circulation, as applicable. There is significant public health interest in verifying the effectiveness of a correction or removal despite any potential redundancy of both finished device component manufacturers and convenience kit manufacturers submitting Part 806 reports for initiation of corrections and removals, including recalls, of the finished device and of a kit containing the finished device as a component.[19]

Q7: What are the responsibilities of a convenience kit manufacturer as a consignee if the manufacturer of a finished device component has initiated a recall under 21 CFR Part 7?

A: The manufacturer or importer of a convenience kit containing a finished device component subject to a recall under 21 CFR Part 7 is a consignee of the finished device component being recalled.[20] Under Part 7, consignees who receive a recall communication should carry out the instructions of the recalling firms and, where necessary, extend the recall to their own consignees in accordance with sections 7.49(b) and (c).[21] The convenience kit manufacturer is also responsible for reporting its correction or removal, when it meets the reporting requirement criteria.[22]

Q8: What if the manufacturer of a finished device component contained within a convenience kit has already reported a death or serious injury caused by that finished device component pursuant to 21 CFR Part 803? Is the convenience kit manufacturer or importer also required to report that death or serious injury pursuant to 21 CFR Part 803?

A: Yes. Manufacturers of medical devices must report to the FDA as required by 21 CFR Part 803. Convenience kit manufacturers or importers have 30 calendar days to report any reasonably known information that suggests a finished device component may have caused or

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[19] 21 CFR 7.49(d) and 820.160. *See also* Guidance for Industry and FDA Staff, Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, March 2022. On February 2, 2024, FDA issued a final rule amending the device quality system (QS) regulation, 21 CFR part 820, to align more closely with international consensus standards for devices. FDA also made conforming amendments to 21 CFR part 4 (89 FR 7496). This final rule will take effect on February 2, 2026. Once in effect, this rule will amend the majority of the current requirements in part 820 and incorporate by reference the 2016 edition of the *International Organization for Standardization (ISO) 13485, Medical devices – Quality management systems – Requirements for regulatory purposes*, in part 820. As stated in the final rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. When the final rule takes effect, FDA will also update the references to provisions in 21 CFR part 820 in this FAQ to be consistent with that rule.

[20] *See* 21 CFR 7.3(n) and 806.2(c).

[21] 21 CFR 7.49(d). *See also* Guidance for Industry and FDA Staff, Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, March 2022.

[22] 21 CFR 806.10(a).

contributed to a death or serious injury.[23] Convenience kit manufacturers or importers must also report under Part 803 if they become aware of a malfunction of a device used as a finished device component that may cause or contribute to a death or serious injury if the malfunction were to recur.[24]

Reasonably known information includes any information you can obtain by contacting a user facility, importer, or other initial reporter; any information in your possession; or any information that you can obtain by analysis, testing, or other evaluation of the device.[25]

Convenience kit manufacturers are responsible for obtaining and submitting to the FDA information that is incomplete or missing from reports submitted by initial reporters.[26]

Q9: Should manufacturers or importers of convenience kits fix their kits if a finished device component requires correction or removal?

A: If a convenience kit contains a violative device, the convenience kit is itself violative. The manufacturer or importer of a convenience kit containing a finished device component subject to a recall under 21 CFR Part 7 is a consignee of the finished device component being recalled.[27] Under Part 7, consignees who receive a recall communication should carry out the instructions of the recalling firms and, where necessary, extend the recall to their own consignees in accordance with sections 7.49(b) and (c).[28]

Q10: What information must the convenience kit manufacturer submit to the FDA regarding its correction or removal?

A: Under 21 CFR Part 806(Medical Devices; Reports of Corrections and Removals), manufacturers or importers must submit a Report of Correction or Removal to FDA for any correction or removal of a medical device that was initiated by such manufacturer or importer to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device that may present a health risk, with certain exceptions.[29] The report must include the following information[30]:

1. Registration number, date the report is made, sequence number (001, 002, etc.), "C" for Correction or "R" for Removal.

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[23] 21 CFR 803.40(a) and 803.50(a)(1).
[24] 21 CFR 803.40(b) and 803.50(a)(2).
[25] 21 CFR 803.40(a) and (b), 803.50(b)(1).
[26] 21 CFR 803.20(a)(3); 803.50(b)(2); 803.52(f)(11).
[27] *See* 21 CFR 7.3(n) and 806.2(c).
[28] 21 CFR 7.49(d). *See also* Guidance for Industry and FDA Staff, Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, March 2022.
[29] 21 CFR 806.10(a).
[30] 21 CFR 806.10(c).
See also https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices#5, last visited 10 Jan 2025.

2. Name, address, phone number, and contact person of the firm responsible for conducting the correction or removal.

3. Brand name and common name of the device and intended use.

4. FDA marketing status, i.e., 510(k), PMA, preamendment status and device listing number.

5. Model/catalog number, lot/serial number, and Unique Device Identifier (UDI).[31]

6. Manufacturer's contact information (name, address, phone number, contact person) if different from item #2 above.

7. Description of event(s) and the corrective and removal actions that have been and are expected to be taken.

8. Any illness or injuries that have occurred with the use of the device. If applicable, include any Medical Device Report (MDR) numbers submitted under 21 CFR Part 803.

9. The number of devices subject to the correction or removal.

10. Date of manufacture or distribution; expiration date or expected life.

11. Name, address, and telephone number of all consignees (domestic and foreign) and the dates and number of devices distributed to each consignee.

12. A copy of all communications regarding the correction or removal.

13. A statement as to why any required information is not available and a date when it will be submitted.

Q11: Should convenience kit manufacturers also submit labeling information with their Report of Correction or Removal?

A: FDA recommends that you include labeling, which includes the individual package label, with your Reports of Corrections and Removals.[32]

Q12: How do convenience kit manufacturers submit the Unique Device Identifier (UDI) in the Report of Correction or Removal?

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),[33] model, catalog, or code

[31] A "Unique Device Identifier" is a numeric identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 830.20. *See* 21 CFR 830.3.
[32] *See* Guidance for Industry, Product Recalls, Including Removals and Corrections, March 2020.
[33] A Universal Product Code (UPC) is acceptable only for Class I devices. *See* 21 CFR 801.40(d).

number of the device and the manufacturing lot or serial number of the device or other identification number.[34] We recommend the following format for submitting this information: [35]

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)

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 electronic spreadsheet file with separate columns for each data element you provide, grouped by UDI-DI as suggested above.

[34] 21 CFR 806.10(c)(5).
[35] *See* Medical Device Recalls and Reports of Corrections and Removals, Part 7, Part 806: Frequently Asked Questions.