On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, 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 Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the final rule issued on February 2, 2024. While this guidance discusses recall procedures and requirements, manufacturers should be aware that the QMSR includes updated quality management system requirements that may impact recall-related processes for medical devices or combination products.

FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

Product Recalls, Including Removals and Corrections

Guidance for Industry

The FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov/. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2003-D-0146.

For questions regarding this guidance or additional copies, contact the Office of Regulatory Affairs (ORA) Office of Strategic Planning and Operational Policy (OSPOP) at ORAPolicyStaffs@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
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Center for Tobacco Products
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MARCH 2020

Product Recalls, Including Removals and Corrections

Guidance for Industry

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Product Recalls, Including Removals and Corrections

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction:

This guidance document is intended to provide guidance and recommendations to FDA-regulated industry regarding what information firms should give to the Food and Drug Administration (FDA) and how they should notify their customers about product recalls. This guidance is intended to assist those members of industry regulated by the FDA in handling most aspects of a product recall, as well as some removals and corrections which do not meet the definition of a recall under 21 CFR 7.3. The guidance includes a checklist of documentation and information that industry can provide to the FDA that will be used by FDA to evaluate, classify, monitor and audit product recalls. Various statutory provisions and regulations, described below, authorize the FDA to require recalls of certain products in particular circumstances. Additionally, subpart C of part 7 of FDA regulations (21 CFR 7.40-59) provides general guidance for the voluntary recall of products, including those recalls initiated by a firm on its own and at the FDA's request. This guidance provides more specific recommendations and applies to voluntary and, to the extent that the guidance does not conflict with statute or regulation, mandatory recalls of all FDA-regulated products (i.e., food, including animal food; drugs, including animal drugs; medical and radiological devices and products; cosmetics; tobacco products; and biological products.)

Certain statutory provisions authorize mandatory recalls of infant formula (FD&C Act § 412(e)-(g) [21 U.S.C. § 350a(e)-(g)]), medical devices (FD&C Act § 518(e) [21 U.S.C. § 360h(e)]),

food (FD&C Act § 423 [21 U.S.C. § 350l]), tobacco products (FD&C Act § 908(c) [21 U.S.C. § 387h(c)]), electronic products (FD&C Act § 535 [21 U.S.C. § 360ll]), controlled substances (FD&C Act § 569D [21 U.S.C. § 360bbb-8d]), and biological products (Public Health Service Act § 351(d) [42 U.S.C. § 262(d)]). Additionally, FDA regulations set forth specific requirements for mandatory infant formula recalls (subpart E of 21 CFR part 107), medical device corrections and removals (21 CFR part 806), mandatory device recalls (21 CFR part 810), electronic product notifications and corrections (21 CFR parts 1003 and 1004) and mandatory recalls for human cells, tissues, and cellular and tissue-based products (subpart F of 21 CFR part 1271). In addition to the requirements in these statutory provisions and regulations, the guidance's specific recommendations may also be useful for these types of recalls. In the context of a mandatory recall, those conditions in the guidance that are set forth in a statute and/or regulation are requirements, rather than recommendations.

The FDA believes that expediting recall activities is vital . Recalling firms are urged to notify the appropriate FDA Division Recall Coordinator (DRC) or Center contact as soon as a decision is made that a recall is appropriate and, if feasible, prior to the issuance of a notice to the public or written communications to customers. To locate your recall coordinator, please check the following website: https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators.

After the decision to recall is made, we recommend that you establish communication with a DRC or Center contact and submit the information outlined in this guidance to your FDA contact as soon as possible. We also recommend that you submit information as it becomes available to you rather than waiting until all applicable information is ready. This will allow the FDA the opportunity to review and comment on your recall strategy and to offer guidance and assistance in your recall process.

FDA guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidance means that something is suggested or recommended, but not required.

II. Recall Information Submission to the FDA

We recommend that you include the following information in your recall submission to the FDA, as applicable to the type of product being recalled:[1,2]

1. PRODUCT INFORMATION. We recommend you provide the following:
    - Product name (include brand name and generic name)
    - Model, catalogue, or product order number(s)
    - Product image
    - Description of the product
        - Include if the product is powder, liquid, tablet, capsule, etc.
        - Include the intended use or indications.
            - For animal products, include the intended species and life stage
        - If the product is perishable, include the expected shelf life.
        - Include the type of packaging (i.e., box, flexible plastic, glass, bulk).
        - Two complete sets of all labeling. Include:
            - Product labeling (including all private labels)
            - Individual package label
            - Case label (photocopy acceptable)
            - Package inserts
            - Directions for use
            - Promotional material (if applicable)

Additional recommended information for ***Drug*** recalls:

[1] The recommendations in Section II do not apply to products regulated by FDA's Center for Biologics Evaluation and Research (CBER). CBER has established the Direct Recall Classification program as the primary means by which firms communicate with CBER regarding a recall. Further information on the Direct Recall Classification program may be found at https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm172970.htm.

[2] Some information is required to be reported for certain products, such as medical device corrections and removals under 21 CFR 806.10. Firms should be familiar with mandatory reporting requirements specific to their product even if they are not noted in this guidance.

- NDA/ANDA/(C)NADA/ANADA/MIF Number
- NDC Number
- Indicate if the drug is prescription or OTC
- Indicate the strength
- Describe the route of administration
- Blue Bird label (for Type A medicated articles for animals)

Additional recommended information for ***Medical Device*** recalls:

- 510(k)/IDE/PMA number
- Specifiying whether the medical device is for human and/or animal use

Additional recommended information for Electronic Product notifications and corrections, if applicable:

- Provide responses to the requirements of 21 CFR 1003 and 1004
- Performance Standard

2. CODES (Production Identification Numbers). We recommend you provide the following:

    - Lot/Unit Numbers
        - NOTE: If "all lots" are involved or the product is not coded, explain how non-recalled, or reintroduced product may be distinguished from product subject to recall.
        - Provide an explanation of the lot number coding system, including specific codes for impacted products
    - Expiration date(s) or use-by date(s) or expected shelf life of product.
    - Serial numbers (medical devices)
    - UPC codes
    - UDI (if applicable)
    - Product Code (medical devices/electronic products)

3. RECALLING FIRM. We recommend you provide the following:

-
- Firm name, address, city, state, zip code
- The firm type (e.g., manufacturer, importer, broker, repacker, own-label distributor)

Contacts for Recalling Firm:

- Name, title, phone number, fax number, and e-mail address for recall contact (the person corresponding with FDA about the recall)
- Name, title, address, phone number, fax number, and e-mail address of the most responsible individual (e.g., owner, plant manager, agent-in-charge)
- Name, title, phone number, fax number, and e-mail address for public contact

4. MANUFACTURER. We recommend you provide the following:
   - Firm name, address, city, state, zip code
   - FDA registration number, ifapplicable.
5. IDENTIFY THE FIRM RESPONSIBLE FOR THE VIOLATION/PRODUCT PROBLEM. We recommend you provide the following:
   - Firm name, address, city, state, zip code
6. REASON FOR THE RECALL. We recommend you provide the following:
   - The date the firm made the decision to conduct a recall
   - Explain in detail how the product is violative.
   - Explain how the violation affects the performance and safety of the product. (Also see #7, Health Hazard Assessment.)
   - If the recall is due to the presence of a foreign object, describe the foreign object's size, composition, hardness, and sharpness.
   - If the recall is due to the presence of a chemical contaminant (e.g., cleaning fluid, machine oil, paint vapors), explain the level of contaminant in the product. If applicable, provide the labeling, a list of ingredients and the Safety Data Sheet for the contaminant.

- If the recall is due to a failure of the product to meet product specifications, provide the specifications and report all test results. Provide copies of any sample analysis.
- If the recall is due to the presence of a pathogen, provide the test results if requested.
- If the recall is due to a label issue (e.g., a missing or inaccurate ingredient list), provide and identify the correct and incorrect label(s), description(s), and formulation(s).
- Explain how the problem occurred and the date(s) it occurred.
- Explain how the problem was discovered and the date it was discovered.
- Explain if the problem affects all units subject to recall, or just a portion of the units in the lots subject to recall.
- Explain why this problem affects only those products/lots subject to recall.
- Provide detailed information on complaints associated with the product/problem, such as reports of adverse events:
  - Date(s) of complaint(s)
  - Number of complaints
  - Description(s) of complaint(s) – include details of any injury or illness and, if medical attention was sought, any confirmed diagnoses
  - Lot Number(s)/Serial Number(s) involved
  - Medical Device Complaints – include copies of MedWatch-MDRs
- If a state agency is involved in this recall, identify the agency and a contact.
- Drug recalls (NDA/ANDA/(C)NADA/ANADA/Index Listed products) - provide details for any Field Alert submitted

7. HEALTH HAZARD ASSESSMENT. We recommend you provide the following:
   - Your assessment of the health hazard associated with the violation.
     - NOTE: A recall decision does not depend solely on the health risk of the product. Violative products where no health hazard exists are still in violation of the law and may warrant being voluntarily recalled.

8. VOLUME OF RECALLED PRODUCT. We recommend you provide the following:
    - Total quantity for recall
    - Date(s) produced
    - Quantity distributed
    - Date(s) distributed
    - Quantity held by recalling firm and its distribution centers.
    - How the product is being quarantined
    - If the information is readily available, estimate the amount of affected product remaining in the marketplace for the following direct accounts consignees (customers you sell directly to):
        - wholesale level
        - distributor level
        - retail level
        - pharmacy, clinic, or veterinary level (drugs)
        - consumer or user level, where appropriate (e.g., medical devices)
    - The status/disposition of marketed product, if known, (e.g., used, implanted, used in further manufacturing, or destroyed).
9. DISTRIBUTION PATTERN. We recommend you provide the following:
    - Number of direct accounts by type, for example:
        - wholesalers/distributors
        - repackers
        - manufacturers
        - retail
        - pharmacy/clinic/veterinarian
        - users (medical devices – hospitals, clinics, laboratories)
        - consumers (internet or catalog sales)

- federal government
- foreign (specify whether they are wholesale distributors, retailers or users)

- Geographic areas of distribution, including foreign countries.
- A direct account list (name, address, city, state, contact name, phone number) to the DRC. At minimum, the list should include the "ship to" addresses. If available, provide a copy of this list in a sortable electronic spreadsheet format (e.g., a Microsoft Excel file.) 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) You should include any foreign customers and federal government customers (e.g., USDA agencies, Department of Veterans Affairs, Department of Defense).
    - Indicate what the list represents (i.e., all customers who were shipped recalled product; all customers who were *sold* recalled product; all customers who *may have* been shipped or sold recalled product because it was sold to them within the applicable time period). Most FDA-regulated products are subject to regulations that require distribution recordkeeping.[3] To the fullest extent available or required, as applicable, you should provide an exact distribution list (not a "may have" list) for the recalled lot(s).
- Was product sold under a government contract? If yes, provide the contract number, contract date and implementation date. If no, indicate so.
- Was product sold to any federal, state, or local agency involved in a school lunch program? If yes, list the customers and provide the quantity sold, the sale date and the shipment date.

In addition, we recommend that you notify both "ship to" and "bill to" customers of the recall so that:

- "Ship to" customers can retrieve the product from their location.

[3] For various requirements related to distribution recordkeeping see, e.g., 21 CFR 211.196 (human and animal drugs); 21 CFR 820.160 (medical devices); 21 CFR 117.139 (human food) 21 CFR 111.475 (dietary supplements); 21 CFR 106.100(g) (infant formula); 21 CFR 113.100(f) (low acid foods); 21 CFR 114.100(d) (acidified foods); 21 CFR 507.38 (animal food); 21 CFR 226.110 (Type A medicated articles); 21 CFR 225.202 (medicated animal feed); 21 CFR 1270.35(c) (human tissue); 21 CFR 1271.265(e) (human cells, tissues, and cellular and tissue-based products); and 21 CFR 1.980(k) and 800.55(k) (post administrative detention recordkeeping).

- "Bill to" customers, if responsible, can initiate the sub-recall.[4]

10. RECALL STRATEGY. We recommend you provide the following:

    - Indicate the level in the distribution chain to which you are extending the recall. (e.g., wholesale, retail, pharmacy, or consumer/user, such as patient or physician)

        - If your recall only extends to the wholesale/distributor level, then we recommend that you explain your rationale for not recalling to retail/pharmacy/user level.

    - Indicate the scope of the recall (i.e., which lots are affected). Indicate your strategy for expanding the scope of the recall should additional lots be shown to be affected.

    - Indicate the method of recall communication (e.g., mail, phone, facsimile, e-mail). We recommend that you include a written communication so customers will have a record of the recall and your instructions.

    - When your customers of the recalled lot(s) can be quickly determined with accuracy and completeness (e.g., via distribution records), we recommend directing recall communications to *only* those customers who received the recalled lots. Although indiscriminately sending the notification to all customers may be simpler, this practice desensitizes customers to recall notices, many of whom receive hundreds of inapplicable recall notices per year. If used, indicate how written communications will be sent to customers (e.g., e-mail, overnight mail, first class mail, certified mail, facsimile).

    - If initial communication is made by phone, provide a copy of the phone script.

    - If you have a web site, consider posting the recall communication on the web site as an additional method of customer notification about the recall. (Note: This is not recommended as a sole means of customer notification.)

    - Provide what you have instructed customers to do with the recalled product.

    - Identify a recall contact for each customer and address recall communications to those recall contacts to reduce the potential for the communication letter to get misdirected.

[4] Sub-recalls occur when a consignee further distributes a recalled product without changing the product. A sub-recall is an action taken by that consignee to notify its own accounts.

- If the product should be returned, refunded, or replaced, explain the mechanics of such process.
- If this recall will create a market shortage that may impact consumers, explain the situation and provide any draft plan to address the shortage.
- Describe your recall effectiveness check strategy. Include your strategy for how to track and identify your customers who fail to respond to your recall communications, and what additional steps you will take to notify non-responsive customers.
- Determine and provide your course of action for out-of-business customers of the recalled product.
- Provide a proposed method for destroying the recalled product, if applicable.
- If the product can be reconditioned (brought into compliance with the law), explain how and where the reconditioning will take place. Please provide details of the reconditioning plan to your FDA contact before implementation. All reconditioning must be conducted under any applicable current good manufacturing practices.
    - Describe how the recalled (i.e., pre-reconditioned) product will be segregated and identified so it is not confused with reconditioned product. Reconditioned product needs to be similarly distinguished from product subject to recall that has not been reconditioned.

In addition, we recommend that:

- You contact your FDA DRC prior to product destruction. The FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers keep adequate documentation of product destruction (regardless of whether destruction was witnessed by an FDA investigator).
- Field corrections (e.g., product relabeling) be performed by recalling firm representatives, or under their supervision and control. We do not recommend that a disinterested party such as a wholesaler or retailer be responsible for field corrections. For drug recalls: misbranded drugs for re-labeling should be returned to the recalling firm.
- You contact your DRC prior to releasing reconditioned goods.

III. Recall Notice to Direct Account Consignees

1. For guidance on issuing public warnings, please reference FDA's guidance on Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C (issued in February, 2019 https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf)

2. GUIDANCE FOR WRITTEN RECALL COMMUNICATIONS TO DIRECT ACCOUNT CONSIGNEES: **Recall communications** should be flagged in large bold print "**URGENT: [insert "FOOD," "DRUG," "MEDICAL DEVICE," etc.] RECALL [or CORRECTION].**" If used, envelopes should be similarly flagged. The terms "market withdrawal" or "stock recovery" should not be used because they have separate regulatory definitions and do not accurately convey the definition of a recall.[5] The FDA recommends that you include the following information in a written recall communication to your direct account consignees:

    a. PRODUCT IDENTIFICATION:

        - Include an accurate and complete description of the product and any codes used to identify the product, e.g., lot/unit numbers, expiration date, serial numbers, catalog numbers, model numbers, UDI, and UPC codes.

        - Consider including a copy of the product label with the recall communication. This could be helpful in identifying and removing the recalled product.

    b. DESCRIPTION OF THE PROBLEM:

        - Identify the reason for the recall and any potential health hazard(s) associated with it. Ensure the statement is clear, directly conveys the risk, and prompts an urgent response by the reader.

    c. DEPTH OF THE RECALL:

        - The recall communication should clearly identify the depth to which the recall is to extend (e.g., wholesale, retail, consumer or user level). For example, if the recall is to the retail level, a statement should read "This recall should be carried out to the retail level."

        - If the product could have been further distributed by your direct account consignees to their customers, then you should include instructions to sub-recall. Sub-recall instructions should also include a statement about the depth of the recall, e.g., "If you have further distributed this product,

[5] See 21 CFR 7.3(g), (h), (j), and (k) for the definitions of "recall," "correction," "market withdrawal," and "stock recovery," respectively.

please identify your customers and notify them at once of this product recall. This recall should be carried out to the retail level."

- If your direct account consignees are instructed to conduct sub-recalls, we recommend that you provide them with the date range that the recalled product was distributed. Wholesalers/ distributors may need this information to identify customers they shipped/sold recalled product to.
- If applicable, consider providing a sub-recall letter with your communication package for your direct account consignees to further notify their sub accounts. This better ensures that the information provided to sub accounts is accurate and complete.

d. INSTRUCTIONS:

- Your recall instructions to your direct account consignees should be clear. For example:
  - Remove product from sale
  - Cease distribution
  - Sub-recall (if appropriate)
  - Return or correct product
- Include a return response card/form. Your direct account consignees should be asked to indicate whether they followed every instruction on the return response card/form. Include a space for the consignee's signature and date.

We recommend that you provide examples of all recall communications (including letters, attachments, envelope) to your DRC.

3. IMPORTANT: All customers in the distribution chain should be ***notified*** of the recall, preferably in writing. Here are some examples of why this is important.

   a. In the case of a human drug recall, the FDA does not believe it is appropriate for a sales representative to visit a doctor's office and remove product without notifying the physician or responsible staff of the recall. Physicians may be treating patients that may suffer or have suffered some adverse effect from the drug subject to recall. With knowledge of the recall and the reason for the recall,

the physician can better evaluate a patient's condition and provide appropriate patient care.

b. In the case of products sold at retail stores, the FDA does not believe it is appropriate for a product salesperson or broker representative to remove product from retail shelves without informing store management of the recall. Failure to inform store management of the recall could result in product that is in storage, in transit to the store, or returned by customers, being offered for sale at a later time. The salesperson or broker representative may not have knowledge of or access to the recalled products stored in back rooms. Recalled products that are in-transit to the store could inadvertently be sold to customers. Recalled products returned by customers could inadvertently be placed back on store shelves.

IV. Evaluation of the Recall

1. EFFECTIVENESS OF THE RECALL:

You should ensure that your recall is effective. Therefore, we recommend that you consider effectiveness checks for every recall. The purpose of an effectiveness check is to verify your recall communication was received by your direct account consignee, and that they understood and followed the recall instructions. The effectiveness check should also verify your recall reached the appropriate level in the distribution chain.

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.

Note: In addition to reviewing the effectiveness checks conducted by a recalling firm, the FDA may also contact a percentage of the firm’s customers (a process referred to as audit checks) as a means of assessing whether the recalling firm and its customers are carrying out the recall. If FDA's audit checks determine the recall to be *ineffective*, the recalling firm (or sub recalling firm if such is the case) will then be requested by FDA to take appropriate actions, such as re-issuing recall communications.

2. RECALL STATUS REPORTS:

You will be asked to provide Recall Status Reports to your 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
- Details of your recall effectiveness checks

3. ROOT CAUSE OF THE PROBLEM THAT RESULTED IN THE RECALL:

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 provide the root cause information to your DRC or appropriate Center contact.

4. CORRECTIVE AND PREVENTIVE ACTIONS TO PREVENT FUTURE OCCURRENCES OF THE PROBLEM:

We recommend that you explain to the FDA the corrective and preventive actions planned or underway that will prevent a similar problem from recurring. You should provide this information to your DRC or appropriate Center contact.

5. TERMINATION OF THE RECALL:

We recommend that you evaluate your recall for termination when all possible customer responses have been received and 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. A final Recall Status Report and documentation of recalled product disposition should be provided to your DRC, after which the FDA will consider formal termination of the recall action. See 21 CFR 7.55 Termination of a recall.

Note: Upon receipt of termination information, the DRC may prepare a recall termination document for center and/or division management concurrence. When concurrence is obtained, the FDA division office will notify the recalling firm that the FDA considers the recall terminated.

Additional Guidance and/or Requirements:

21 CFR part 7, subparts A and C – Recalls (general guidelines)
FD&C Act § 412 [21 U.S.C. § 350a] – Requirements for Infant Formulas
21 CFR part 107, subpart E –Infant Formula Recalls
FD&C Act § 423 [21 U.S.C. § 350l] – Mandatory Recall Authority (food)
21 CFR part 1271 – Human Cells, Tissues, and Cellular and Tissue-based Products

Public Health Service Act § 351 [42 U.S.C. § 262] – Regulation of Biological Products
FD&C Act § 518 [21 U.S.C. § 360(h)] – Notification and Other Remedies (medical devices)
21 CFR part 806 – Medical Devices; Reports of Corrections and Removals
21 CFR part 810 – Medical Device Recall Authority
FD&C Act § 908 [21 U.S.C. § 387h] – Notification and Other Remedies (tobacco products)

FD&C Act § 535 [21 U.S.C. § 360ll] – Notification of Defects In, and Repair or Replacement of, Electronic Products

FD&C Act § 569D [21 U.S.C. § 360bbb-8d] – Notification, Nondistribution, and Recall of Controlled Substances
21 CFR part 1003 – Notification of Defects or Failure to Comply (electronic products)
21 CFR part 1004 – Repurchase, Repairs, or Replacement of Electronic Products

For additional information on FDA Guidance for Industry, visit FDA's Guidance for Recalls-Information on Recalls of FDA Regulated Products