Device Correction/Removal Report Model for Industry

To facilitate your recall, we have included the link to our "Recalls, Market Withdrawals & Safety Alerts". This link is intended to provide guidance and instruction to FDA regulated industry regarding product recalls. www.fda.gov/Safety/Recalls/default.htm

"21 CFR Part 806 requires manufacturers and importers to notify FDA of certain device corrections and removals actions. We recommend these be reported to your Division Recall Coordinator electronically. Please also submit the draft letter and recall strategy prior to initiation. It is recommended to not wait until all information is completed, but to submit this information as soon as possible. This "early" notification will allow FDA the opportunity to review and comment on your written notification and to offer guidance and assistance in your recall process."
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=806.10

oradevices1recalls@fda.hhs.gov
When recalling firm (initiating recall) is in: CT, DE, IN, KY, MA, ME, MD, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV and the District of Columbia.

oradevices2recalls@fda.hhs.gov
When recalling firm (initiating recall) is in: AL, FL, GA, IA, IL, KS, LA, MN, MO, MS, NC, ND, NE, SC, SD, TN, WI, Puerto Rico, and the US Virgin Islands.

oradevices3recalls@fda.hhs.gov
When recalling firm (initiating recall) is in: AK, AR, AZ, CA, CO, HI, ID, MT, NM, NV, OK, OR, TX, UT, WA and WY.

Recall Submission to FDA

Report of Corrections and Removal number (CFN or FEI - date - ### - R or C) as required by 21 CFR 806.10(c)(a).

FIRM INFORMATION:
RECALLING FIRM:

- Name
- Address
- Telephone #
- Indicate if your firm is an Own Label Distributor

- Email

TOP FIRM OFFICIAL (e.g. PRESIDENT/CEO)

- Name (include prefix e.g. Mr., Ms., Dr. etc.)
- Address
- Telephone
- Email

MANUFACTURER: (if different from recalling firm), (report whether contract manufacturer information needs to be confidential)

- Name
- Address
- Telephone #
- Email
- CFN/FEI

RECALL CONTACT: (person who interacts with Recall Coordinator)

- Name
- Title
- Address
- Telephone #
- Email

PUBLIC CONTACT: (person the public interacts with at the firm)

- Name
- Title
- Address
- Telephone #
- Email

1. What product(s) are you recalling?

2. For each recalled product, please provide the following information(if possible, on a sortable spread-sheet):

    - Brand Name
    - Unique Device Identifier (UDI)[1]

[1]The UDI rule, under 21 CFR 830.300, requires that device identification be submitted to the Global Unique Device Identification Database (GUDID), unless exempted from UDI requirements or an alternative or exception is granted. This data is available for public use via AccessGUDID. Your firm should ensure that device identification information you submit to the GUDID is consistent with the information in all communications about the device throughout its life-cycle, including the Report of Correction or Removal.
Contact the FDA UDI Help Desk if you need assistance with GUDID or more information on the UDI Program.

Please provide all applicable UDI information.

- *If only UDI-DI is being provided, to submit as "UDI-DI:" and the number;*
- *If full UDI is being provided, to submit as "UDI:" and the number with all parentheses and special characters as provided and DO NOT include any blank spaces between characters* ***within each UDI****.*
- *Please continue to provide all applicable Lot Codes, Serial Numbers, Expiration Date and Manufacturing Date information separately as requested below.*

- If the recalled product is a software, include version number

- Lot codes if applicable
  - **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 your lot number coding system**
- Model Number
- Is it a component?
  - If so, what is it a component of?
- Shelf life
- Expected life
- Indication of use
- 510(k) number
- Is product sterile?
- Is product controlled by software?
- Is this a trackable device?
- Is this an implantable device?
- Total Quantity Manufactured
- Manufacturing Date ranges (beginning and ending dates)
- Quantity Distributed (per product)
- Distribution Date ranges (beginning and ending dates)
- Amount of product quarantined

3. Include a complete copy of all labeling (preferably in color and .jpeg format). Include product

inserts and any information sheets for all products being recalled.

4. Identify Reason for Recall

5. Please answer the following questions regarding your recall:

    - Firm Awareness Date
    - Recall Initiation Date
    - How was the problem discovered?
        - **If discovery was through testing, please provide copies of the analysis**.
    -
    - Any reported illness or injuries?
    - Did you conduct a Health Hazard Evaluation (HHE)?
        - **If so, please include a copy.**
    - Have you determined a root cause for the problem?
    - Number of complaints received (provide copies)
    - MDR Submitted? (provide copies)
        - If so, how many:
            - Deaths?
            - Injuries?
            - Malfunctions?
            - Other?

6. Distribution Details

    - Please provide a complete listing of all locations where this product was sent to. **Please include the following information in Microsoft Excel (each in its own cell): Customer name/ physical address/ city/ state / zip code /telephone (please avoid duplicate consignee locations)**

        - Please separate foreign and domestic consignees
        - Please separate Military and Government consignees

Please fill in the table below as to the number of each type of consignee, for U.S. only, including Government consignees.

Consignees	Approx. Number	Consignees	Approx. Number
Distributor		Repacker/Relabeler	
Retailer		Direct Accounts	
Institution		Veterans Administration	
Medical Facility		Department of Defense	
Internet Sales		Manufacturer	
Physician		USDA	
Consumer/Patient		Other	

7. Recall Strategy

- Indicate the customer level to which you are extending the recall. (i.e. wholesale-distributor/retail/user level)
- If your recall only extends to the wholesale/distributor level, please explain your rationale.
- Indicate the method of notification (i.e. mail, phone, facsimile, e-mail, letter, visit), and the date it was first issued. It is advisable to include a written notification so customers will have a record of the recall and your instructions.
- Indicate how letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile), and whether a third party recall company is being used (provide name and address of third party).
- If initial notification is by phone, you must provide a copy of the phone script to FDA and the date(s) that notification was attempted and/or achieved.
- If you have a web site, you should consider posting the recall notification on the web site as an additional method of recall notification. (Note: This is not recommended as a sole means of customer notification.)
- Report on what you have instructed customers to do with the recalled product.
- How are you determining if the recall is effective? What effectiveness checks are you conducting?

- **Effectiveness checks are your means of evaluating the effectiveness of your recall. If your effectiveness checks indicate that the recall notification was not received, read and/or instructions followed, then you should take necessary steps to make the recall effective. These steps may involve sending out a follow up notification that better identifies the product, better explains the problem and/or provides better instructions to customers.**

- How are you planning on following up with customers who do not respond?
- Determine and provide your course of action for out-of-business distributors.
- If the product is to be "reconditioned", provide details of the reconditioning plan and seek concurrence by your Recall Coordinator FDA prior to implementation.

8. What are you planning to do with any returned product?
    - How are you going to store it?
    - What is the destruction plan? Provide the details (date, method, and location) prior to destruction in the event FDA would like to witness the action.

9. What preventative measures have you taken or are planning to take to prevent this event from occurring again? Please provide a copy of the final CAPA.

10. If a press release was issued or will be issued, please submit a copy. In a situation where the product may pose a significant health hazard and recalled product is in the hands of consumers, a press release is usually appropriate. Issuance of a press release should be the highest priority and it should be issued promptly. Unique situations will be handled on a case-by-case basis.
    - You should consult with your respective Recall Coordinator before issuance of a press release whenever possible.
    - Submit press release to an appropriate newswire that will reach all intended consumers.
        - For example: The AP- send the press release in the body of an email (no attachments) to info@ap.org

NOTE: For those recalls where FDA believes a Press Release is warranted, the Agency may issue a Press Release if the firm has failed to do so, or if the firm-initiated press release is not adequate.