U.S. FOOD & DRUG ADMINISTRATION

Understand the Recalls Process from Initiation to Termination!

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Polling Question #1

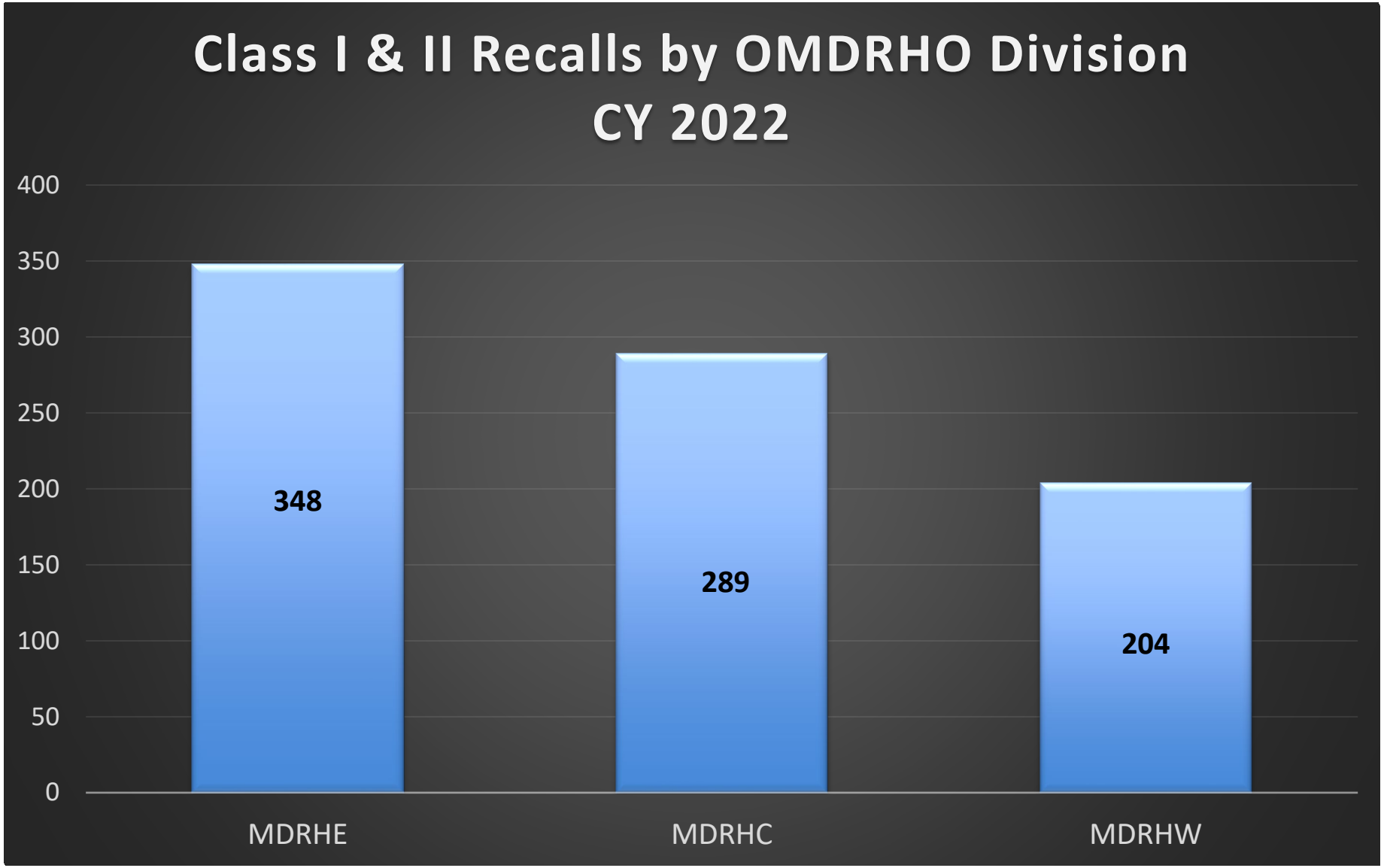
Has your company conducted a medical device recall in the last 5 years?

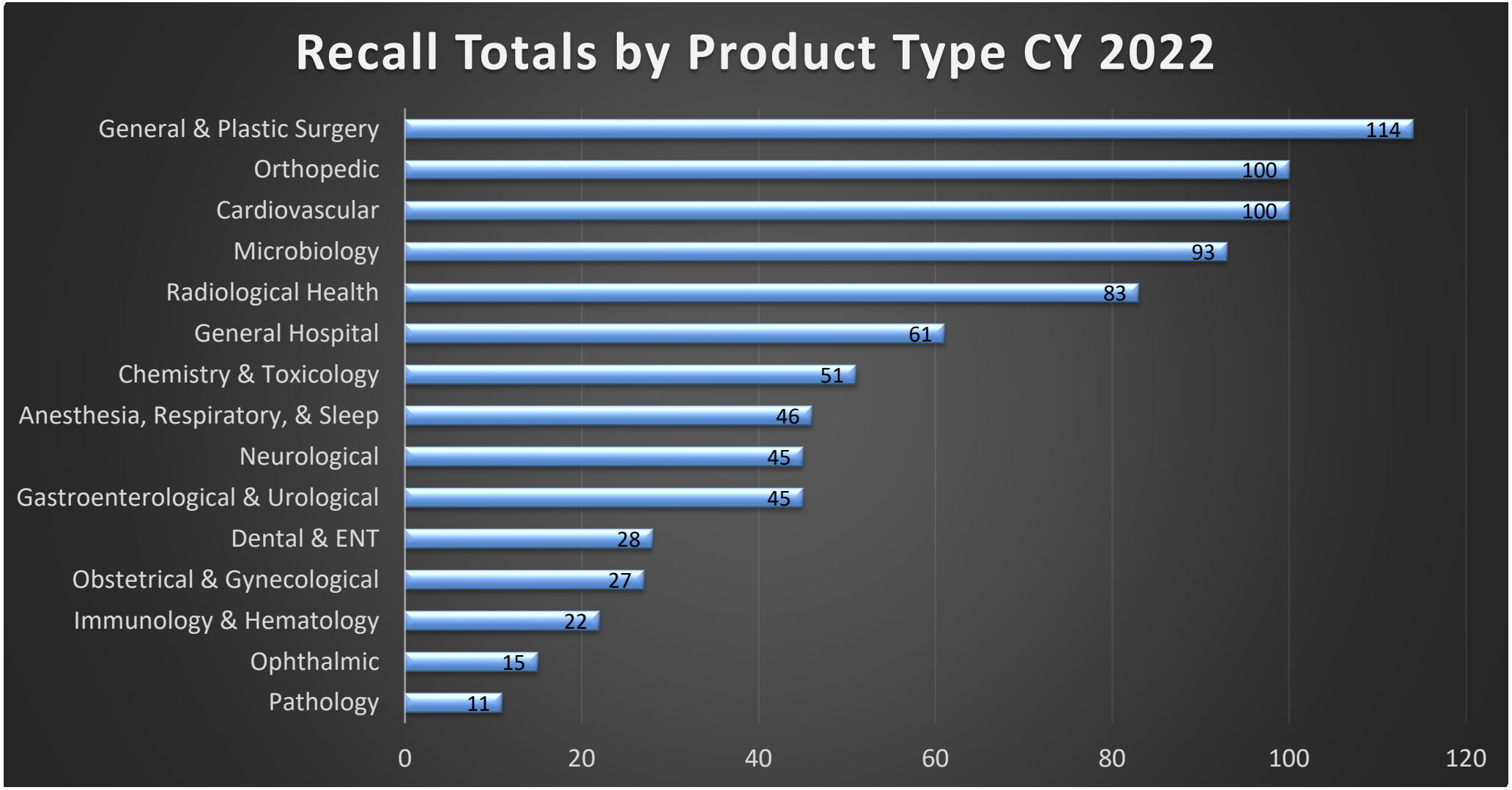
1. Yes
2. No
3. I do not know.

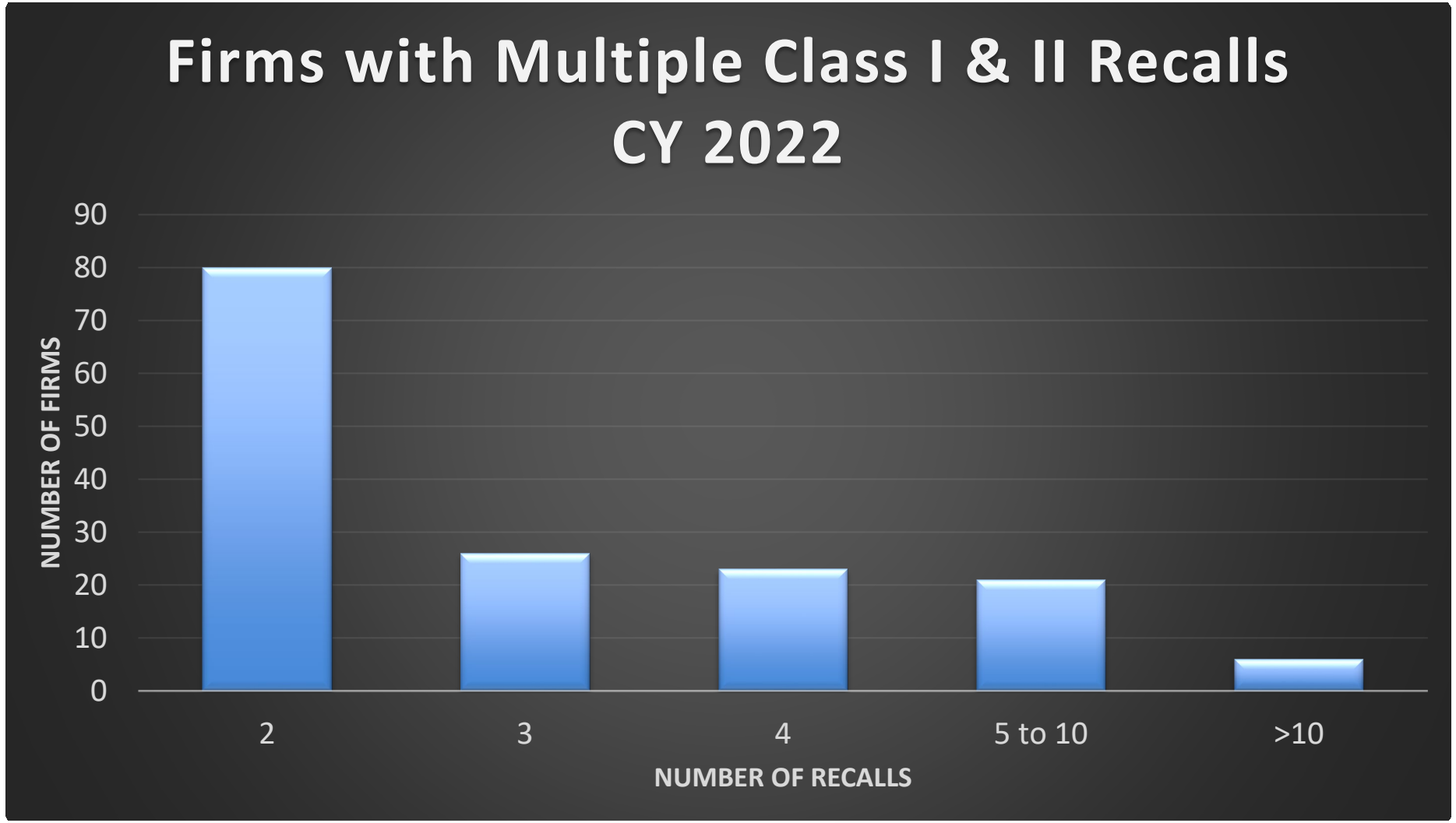
Correction and Removal (Recall) Analysis

Background

- CY 2022 - **841** Class I & II Recalls
- All OMDRHO Divisions included in analysis


Class I & II Recalls by OMDRHO Division
CY 2022
400
350
300
250
200
150
100
50
0
348
289
204
MDRHE
MDRHC
MDRHW


Recall Totals by Product Type CY 2022
General & Plastic Surgery
Orthopedic
Cardiovascular
Microbiology
Radiological Health
General Hospital
Chemistry & Toxicology
Anesthesia, Respiratory, & Sleep
Neurological
Gastroenterological & Urological
Dental & ENT
Obstetrical & Gynecological
Immunology & Hematology
Ophthalmic
Pathology
114
100
100
93
83
61
51
46
45
45
28
27
22
15
11
0
20
40
60
80
100
120


Firms with Multiple Class I & II Recalls
CY 2022
NUMBER OF FIRMS
90
80
70
60
50
40
30
20
10
0
2
3
4
5 to 10
>10
NUMBER OF RECALLS

New Fillable Form for 806 Submissions

Comments due by 06/12/2023

Polling Question #2

Do you know who is responsible for reporting Correction & Removals (806 Reports), submitting status reports and requesting termination of a recall at your firm?

1. Yes
2. No

Where to Begin

FDA GUIDANCE, RECALL LETTER & 806 REPORT

Polling Question #3

Do you feel comfortable with navigating the FDA website for recall information?

1. Yes
2. No

FDA.gov

1. Recall Resources Recall Resources | FDA
2. Industry Guidance Industry Guidance For Recalls | FDA
3. Recalls, Corrections and Removals (Devices): Recalls, Corrections and Removals (Devices) | FDA
   - Links to applicable regulations
   - Definitions/Classifications
   - Elements of recall strategy
   - Recall letter
   - 806 Reports

FDA.gov (cont'd)

4. Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C | FDA
5. Product Recalls, Including Removals and Corrections Product Recalls, Including Removals and Corrections | FDA

FDA.gov – Recall Letter

- Medical-Device-Model-Recall-Letter-and-Response-Form.doc (fda.gov)
- Important Elements
  - Clear reason for recall
  - Any deaths/injuries
  - Clear hazard explained
  - Actions taken by customer and firm
  - Response form

Company Name
Date (Month, Day, Year)

URGENT:[1] MEDICAL DEVICE RECALL[2]

<PRODUCT NAME>

(1) Attention to Customer:

(2) Purpose of this letter

The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X

(3) Reason for the Voluntary Recall:

Identify the product concerns/problems, whether actual or potential, in detail (For example, what happens when the device fails). Include the following information, if available:

- **Frequency of failures and complaints** (for example, "We are aware of [number of] product failures and [number of] complaints associated with the problem.")
- **Magnitude of the error, if applicable** (for example, the failure results in values 15% lower than true values)
- **Adverse events** (that is, injuries, deaths)

- **Frequency of failures and complaints** (for example, "We are aware of [number of] product failures and [number of] complaints associated with the problem.")
- **Magnitude of the error, if applicable** (for example, the failure results in values 15% lower than true values)
- **Adverse events** (that is, injuries, deaths)

[1] Recommended for Class I and II recalls. "Urgent" should be noted on both the letter and envelope as per 21 CFR 7.49(4)(b).

(4) Risk to Health:

4a) Explain how the device failure or problem will affect patients, health care providers, or other persons who are exposed to the device. If the device failure can cause injuries, delays in surgical procedures, or other delays in treatment or therapy, provide an explanation of why that is so.

(4) Risk to Health:

4a) Explain how the device failure or problem will affect patients, health care providers, or other

(6) Product and Distribution Information: This table is not limited to the information listed below; please insert additional information as applicable. Photographs of the product are optional.

Product and Distribution Information Table

Product Names; Unique Device Identifier (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number	Manufacturing/Distribution Dates	Expiration Date (MM/DD/YYYY)	Quantity

(7) Type of Action by the Company:

What is the firm doing to correct this issue? – (for example, system updates, removal, and change in labeling). When will these corrective actions be taken by the company (short and long-term)?

- Failure Investigation findings:

- Failure Investigation findings:

(8) OTHER INFORMATION:

- Contact information for questions
- Attachments of Acknowledgement and Product Replacement Forms (separate sheets)

Authorized by:
Name: (Print)

Signature:

Title:

Contact Information: Include Days/Hours Available (with Time Zone) for calls such as, Monday through Friday, 8:00 AM to 4:30 PM, Eastern Time. Add toll-free number if available. Add website information if available.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:
Customer Name
Street Address
Town, State, Zip Code

PRODUCT NAME

Lot/Serial numbers:

I have read and understand the recall instructions provided in the <date of> letter. Yes _ No_

Any adverse events associated with recalled product? Yes _ No _

If yes, please explain:

_____
_____
_____
_____

Was this device implanted? (If yes, please **specify the implant dates, the quantities implanted, and provide available tracking information**).

Affected Product Information: Include information that is applicable for affected product.

Affected Product Information Table					
Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number shipped to Customer	Quantity in inventory	Quantity relabeled	Quantity destroyed/ returned

Return Response Box:
Please provide any additional information, if applicable.

Distributors:
I have checked my stock and have quarantined inventory consisting of _____ <units, cases, etc.>.

I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**); <or>
Attached is a list of customers who received/may have received this product. Please notify my customers.

Questions: (when applicable)

☐ Please have Customer Service contact me.

Signature of Receipt _____

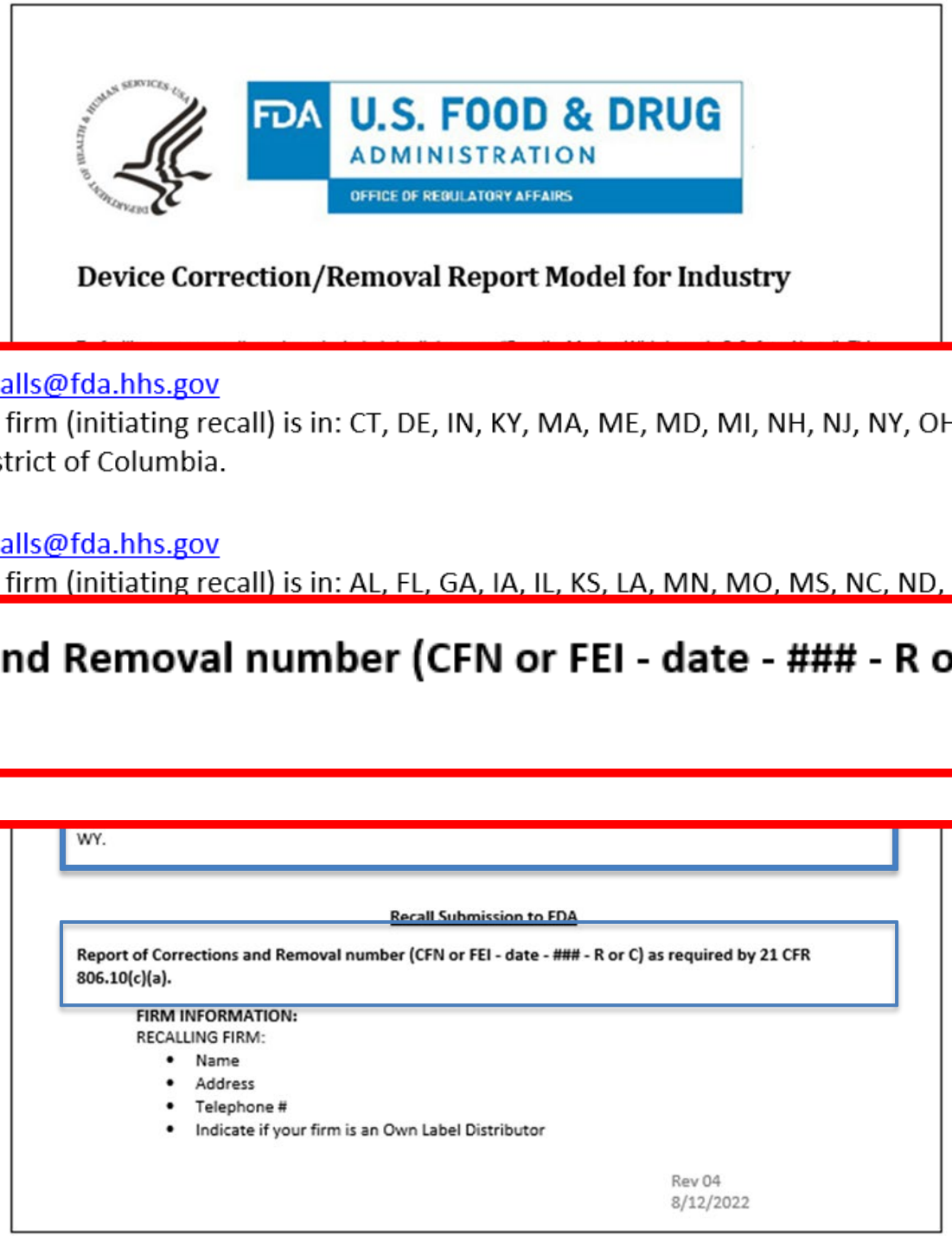
Name/Title	
Telephone	
Email address	

PLEASE FAX COMPLETED RESPONSE FORM TO: Tel. # < >, ATTN: < >
OR MAIL TO: FIRM NAME AND ADDRESS

Polling Question #4

Do you feel confident in knowing what to submit in your “806 Report” or recall package?

1. Yes
2. No



U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Device Correction/Removal Report Model for Industry

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, WY.

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

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

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- 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.

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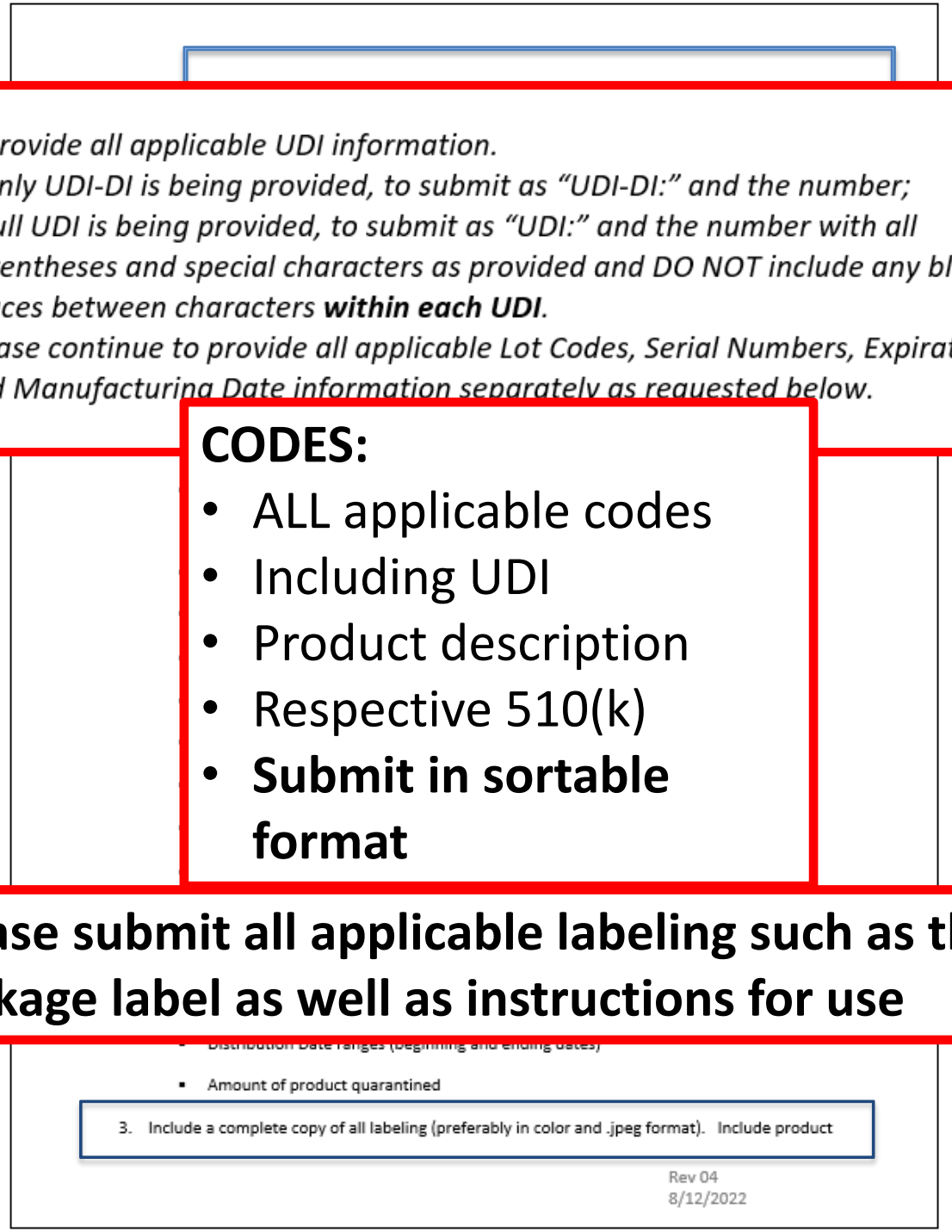

Please provide all applicable UDI information.

- *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.*

CODES:

- ALL applicable codes
- Including UDI
- Product description
- Respective 510(k)
- **Submit in sortable format**

Please submit all applicable labeling such as the package label as well as instructions for use

- Amount of product quarantined

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

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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

ies of the analysis.

- Did you conduct a Health Hazard Evaluation (HHE)?
  - **If so, please include a copy.**

- Sortable format
- Customer name
- Complete physical address
- Telephone and contact (if possible)
- Duplicates removed
- Number of units distributed to each consignee

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

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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	

Firms should explain how they will demonstrate a recall is effective, specifically

- Consignees received notification
- Followed instructions in notification
- How non-responding consignees are addressed

❖ **FDA expects firms to take necessary steps to make a recall effective**

- 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?

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- 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.

- 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.

- 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.

How’s It Going?

STATUS REPORTS

Polling Question #5

About how long does it take to complete a recall?

A. 1 month
B. 6 months
C. 1 year
D. > 1 year

What does 21 CFR Part 7 say?

- **§ 7.53 Recall status reports.**
- (a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.
- (b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:
  - (1) Number of consignees notified of the recall, and date and method of notification.
  - (2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
  - (3) Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).
  - (4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
  - (5) Number and results of effectiveness checks that were made.
  - (6) Estimated time frames for completion of the recall.
- (c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

What goes into a status report?

- Show monthly progress in your recall strategy
  - Effectiveness of Notification
  - # Products Corrected or Removed
  - Estimated completion date
- Updates to root cause or CAPA

Tell us if…

- You are going to change your strategy
- You need to expand your recall to include additional products or lots
- You have rework or destruction planned
- There are new points of contact
- If there are additional consignees or a reduction, and why

Where to send the status report?

- Your friendly division recall coordinators
  - Division 1: ORADevices1Recalls@fda.hhs.gov
  - Division 2: ORADevices2Recalls@fda.hhs.gov
  - Division 3: ORADevices3Recalls@fda.hhs.gov
- Do NOT send them
  - To individual DRC's
  - To FDA_Recalls@fda.hhs.gov

Status Report Example

Subject Line: RES 99999 – Status Report – April 2023

Body: To whom it may concern, please see attached our monthly status report for RES 99999, for [Product Name]. We are starting to conduct effectiveness checks and will continue to submit monthly status reports until the recall is completed.

Attachments: Status Report

Status Report Example

Date	Method	# Consignees Notified	# Consignees Responding	# Consignees Nonresponding	Total % Consignees Responded
1/20/23	Email	50	20	30	40%
1/27/23	Email	30	10	20	60%
2/12/23	Phone Call	20	15	5	90%

- Out of 100 distributed products, 58 have been returned and are in quarantine awaiting disposition.
- Estimated completion date: July 31, 2024.
- CAPA 015 was opened for this recall and is still in progress.

*****MAKE SURE THE MATH MAKES SENSE*****

If you forget to submit status reports…

- We will remind you!
- Remember to send status reports to Division inboxes
- If termination request was accepted, no need for further status reports unless otherwise instructed

Are We Done Yet?

TERMINATION

What does 21 CFR Part 7 say?

- **§ 7.55 Termination of a recall.**
- (a) A recall will be terminated when the Food and Drug Administration 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. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

- (b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

Termination Requests Should Include…

- Overall response rate
- Number of devices corrected or removed
  - Corrections *must* be completed before termination!
- Final disposition of returned products
  - Rework records
  - Destruction records
- Root cause
- Corrective & Preventive Actions that will prevent recurrence of the issue

Effectiveness Checks

- Need to show that the customer
  - Received your notice
  - Understood your notice
  - Has taken the recommended actions
- FDA may request a sample of effectiveness checks for review

Ways to Show Effectiveness

- Completed customer response forms
- Records of service
- Return records
- Communication with customers
  - Email chains
  - Call logs
- Read receipts or certified delivery receipts on their own do not show effectiveness

Polling Question #6

What methods do you use to contact consignees?

A. Mailed letters (USPS, FedEx, UPS, etc.)
B. Phone call
C. Email
D. Visit
E. A combination of the above
F. I don’t know

Making a Good Faith Effort

- 3 attempts
- 2 or more methods
  - Mail
  - Email
  - Phone
  - Visit
- Document all attempts to contact customers

Termination Request Example

- **Subject Line:** “RES 99999 – Termination Request”
- **Body:** “We have completed our customer notification effectiveness checks as well as product disposition. We would like to request termination for RES 99999 at this time.”
- **Attachments:**
  - Final Status Report
  - Summary of Corrective Actions (ex: CAPA)
  - Destruction Documents

Destruction Memo Example

- (On company letterhead)
- “On 3/20/2023, the following units of HealthyWares Cubes were destroyed at ABC Dispo in Detroit, MI, via crushing. Please see attached photos.”

Lot	Quantity
00001	50
00002	50

Before you terminate…

- Did you make a Good Faith Effort?
- Has all product been removed (or corrected)?
- Is the product disposition or correction complete?

No need to be perfect. We'll ask for more information if needed.

U.S. FOOD & DRUG ADMINISTRATION

Thank you for your time

Any questions?