Recall Communication: Medical Device Model Recall Notification Letter

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U.S. Food and Drug Administration
Center for Devices and Radiological Health

Company Recall Requirements

- The recalling company is responsible for promptly notifying each of its affected direct accounts (that is, distributors, contractors, customers) about a recall.

- A recall communication can be in the form of a press release, telephone call, telegram, mailgram, or a first class letter. It is highly recommended that the recalling firm discuss a recall letter with the FDA district office recall coordinator prior to issuing the notification.

www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ucm243982.htm

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm

What is the reason for the company's notification?

- To provide details regarding the product recall
- To supply information to help users identify the product
- To minimize health consequences by providing instructions on what action(s) need to be taken

www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ucm243982.htm

Recall Notification

- First Class Letter should be conspicuously marked, preferably in bold red type, on the letter and the envelope: “URGENT Medical Device Recall."
- The letter and the envelope should be also marked “URGENT" for Class I and Class II recalls and, when appropriate, for Class III recalls.
- Telephone calls or other personal contacts should be confirmed by one of the above methods and/or documented in an appropriate manner.

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm

Company Name
Date (Month, Day, Year)

URGENT:[1] MEDICAL DEVICE RECALL[2]

<PRODUCT NAME>

Customer Name
Device Name
Street Address
City, State, Zip Code

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Risk to Health:

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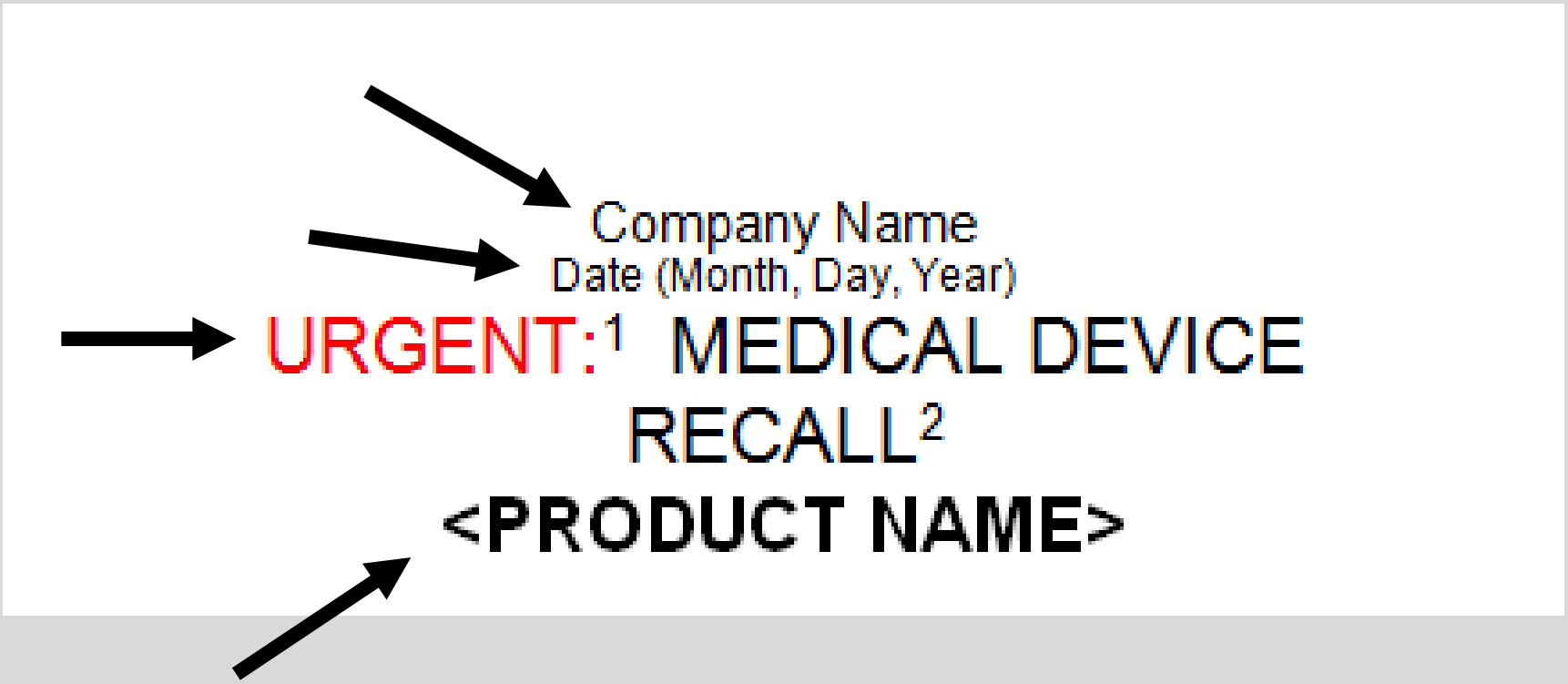
- Failure investigation findings

125.151v1.01, 11/07/11


Company Name
Date (Month, Day, Year)
URGENT:[1] MEDICAL DEVICE
RECALL[2]
<PRODUCT NAME>

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- Failure investigation findings

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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 a toll-free number and a dedicated website address if they are available.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA 1-800-FDA-1088

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Recall Notification Format

- The format, content, and extent of the notification should be commensurate with the recall hazard and strategy.

Sample Acknowledgement Letter

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

Inappropriate Information in a Recall Notification

- Qualification data
- Promotional materials
- Any other statement that may detract from the message

Notification Follow-up

- When necessary, additional communication should be sent to customers who fail to acknowledge receiving the initial notice.

Consignee/Distributor Responsibilities

- Upon receipt of a recall notification, follow the instructions set forth by the recalling firm.
- When necessary, extend the recall to its customers in accordance with the instructions provided by the firm.

Conclusion

- Notification letters must provide clear details regarding the issue and the health risk to the users.
- Information identifying affected products must be easy to find.
- Actions to be taken by the users should be bulleted or numbered to clearly articulate the requirements to minimize risk or impact of affected product.
- Notification should be sectioned to allow the user to quickly see the information needed to react to the recall requirements.

Thank You

- If you have further questions regarding reporting requirements, contact:

  Your local FDA District Recall Coordinator at

  http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

  CDRH's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at

  1-800-638-2041, 301-796-7100 or

  dsmica@ fda.hhs.gov

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