Recall Communication: Medical Device Model Press Release

Ronny Brown
Acting Chief, Recall Branch
Division of Risk Management Operations
U.S. Food and Drug Administration
Center for Devices and Radiological Health

What is a Recall Press Release?

- A Form of Public Warning
  - For urgent situations
  - Brief and to the point
  - Issued **promptly**

www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

When is a Press Release for a device recall recommended?

- When products pose a significant health hazard (Class I Recalls and some Class II Recalls)
- When other forms of notification to consignees may be inadequate (e.g., devices sold directly to consumers)

- It is a policy that press releases are issued for all Class I medical device recalls unless it will not be helpful to the public. For example:
  - When initial consultation between patients and their physicians is essential
  - There is inadequate information to convey risk and appropriate actions
  - When product is limited to a small number of users that are easily identified and reached through targeted contact

www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177312.htm

How can FDA support you in preparing your Press Release?

- Consult your local District Recall Coordinator before issuance whenever possible.
- Use the Medical Device Press Release template in the Regulatory Procedures Manual (RPM).
- Consumers may benefit from the clarity of a joint press release by FDA and your firm.

www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

How can FDA support you in preparing your Press Release?

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

SEC. 705. [21 USC §375] Publicity

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger health, or gross deception of the consumer.

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

How is the information in the Press Release disseminated?

- The FDA Medical Device Recalls webpage
  www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm
- General news media, either national or local as appropriate
- Specialized news media, e.g., professional or trade press.

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

Medical Device Model Press Release:

Medical Device Model Press Release

Company Name **Issues Nationwide Recall of** Product(s) Name(s)

FOR IMMEDIATE RELEASE: **DATE**
Company Address
Telephone/Company Website

Purpose of the Press Release:

On (date) Company Name is initiating a nationwide recall of **quantity and** name of product(s). The **product(s)** have been found to **describe problem**, which **has/potentially** could result in **describe public health risk**. State if there is a related recall.

Consumers who have **product(s)** should **stop using/return/replace/throw away/contact their doctor, etc.**

Product(s) was manufactured from **date to date** and distributed from **date to date.**

The recall includes the following **styles/models/UDI/ID numbers**, (etc.) and **quantity.**

Name of Product UDI Model(s) Serial Number(s) Quantity

Product(s) can be identified by **provide additional details about how product(s) can be identified.**

The firm voluntarily recalled the product(s) after becoming aware of **(fill in)**. FDA has been notified of this action.

Brief explanation of what is known about the problem. Provide number, type and status of any injuries that have been CONFIRMED to date (For example, "No injuries have been reported to date.").

Company is notifying its distributors and customers by **describe method** and is arranging for **return/replacement/retrofit, etc.** of all recalled product(s).

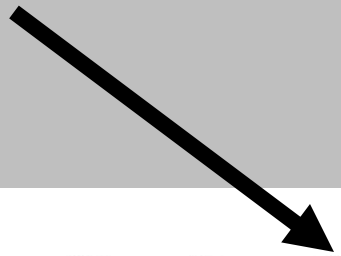
Product(s) was distributed to **describe type of outlets, states/ areas** (Define areas).

Consumers with questions may contact the company at **1-800-xxx-xxxx between the hours of x and x (include time zone) and email if 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

Press Release: Header



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Press Release: Identify Product

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Press Release: What's known about the recall

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

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Press Release: Product Distribution

Company is notifying its distributors and customers by **describe method** and is arranging for **return/replacement/retrofit, etc.** of all recalled product(s).

Product(s) was distributed to **describe type of outlets, states/ geographical area.**

www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177311.htm#SUB7-6-4

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Press Release: Contact Information

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Do not include in Press Release

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

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=810.15

Conclusion

- Press releases must provide clear and concise information concerning the recall health risk to the users.
- Issue your press release promptly
- Contact your District Office with your draft press release to discuss content.

Helpful Links

- **Medical Model Press Release;**
  www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129289.htm
- **ORA District and Headquarters Recall Coordinators;**
  www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm
- **Recalls, Corrections and Removals (Devices);**
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm
- **Title 21 of the Code of Federal Regulations; Part 7 Enforcement Policy (21CFR 7) and Part 806 (21CFR 806), www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm**

Helpful Links

- **Regulatory Procedures Manual (RPM), Chapter7 Recall Procedures;**

  www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177312.htm

- **Guidance for Industry: Product Recalls, Including Removals and Corrections;**

  www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

- **Compliance Activities;**

  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/default.htm

Thank You

If you have further questions regarding reporting requirements, contact:

Your local FDA District Recall Coordinator at

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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