Recall Communication: Medical Device Model Press Release

Ron Brown

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Welcome to CDRH Learn. CDRH Learn is a training program developed by FDA's Center for Devices and Radiological Health. It's designed to bring you training on a wide range of topics that involve the regulation of and policies related to medical devices and radiation products.
I am Ron Brown, the Acting Recall Branch Chief for the Division of Risk Management Operations. Today, I am going to discuss the Medical Device Model Press Release.

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"What is a Medical Device Recall Press Release?"

-- A press release is a form of public warning. Its purpose is to alert the public that a product that is being recalled, presents a serious hazard to health.

-- A press release is used in urgent situations where other means for preventing use of the recalled product appear inadequate.

-- It should be brief and to the point

-- Issuance of a press release should be the highest priority and should be issued promptly. Unique situations will be handled on a case-by-case basis.

More information can be found at the link provided on your screen.

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When is a Press Release for a device recall recommended?

It's recommended when products pose a significant health hazard. Normally, this means Class I Recalls but some Class II Recalls may be included. Also, a press release is recommended recommended when other forms of notification, like phone calls or notification letters, may be inadequate.

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When might a Press Release be delayed?
The FDA may delay public notification of recalls of certain drugs and devices when the agency determines that public notification may cause unnecessary and harmful anxiety in patients, and that initial consultation between patients and their physicians is essential... or, if there is inadequate information available to notify the public at the time.
More information can be found at the link provided on your screen.

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How can FDA support you in preparing your Press Release?

-- You should contact your local District Recall Coordinator before issuance whenever possible.

-- You should use the Medical Device Press Release template in the Regulatory Procedures Manual.

Please also note that publicity may be issued by either the recalling firm or by FDA. Agency policy gives the recalling firm the first opportunity to prepare and issue publicity concerning its recall. However, FDA may also issue press in cases where it is believed that the firm's press release is inadequate, or where the firm fails to issue a press release.

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The FDA, in consultation with the recalling firm, will ordinarily issue publicity.

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

The following information is from Section 705 of the Federal Food Drug and Cosmetic Act regarding Publicity.

Part (b) states: 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 to health, or gross deception of the consumer.

Please understand that this means that when the FDA determines a press release is warranted, it will go out to the public. You, as the manufacturer, should want to be involved.

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How is the information in the Press Release disseminated?

On the Medical Device Recall webpage, you can find the link for a recall's press release. Please note that there are many outlets to use, such as the general news media - either national or local, as appropriate - or specialized news media, for example, Professional or Trade press.

Please note that when the recalling firm decides to issue its own public warning:

-- the FDA requests that you submit your proposed public warning, and plan for distribution of the warning for review and comment. Also,
you may want to send some communication to specific segments of the population, for example: physicians, pharmacists, veterinarians, and hospitals.

Again, make sure to discuss this with the Recall Coordinator in your District Office!

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Now we'll discuss the Model Press Release template that we provide on our website.

It is divided into sections with headers to make it easy to find the information quickly.
First, let's look at the Header.

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Here you want to include the firm's name and the name each product involved in the recall.
Be sure to put this information in bolded text to emphasize that this communication deals with a recalled product.

You should also include:
the date the press release was issued,
-- the complete address, including the zip code. Also include the country if the firm is outside the United States,
--and the company's telephone number & website, if available

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Next, provide the purpose of the press release.

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In the purpose of Press Release,

--include the date the company initiated the recall, and which products are affected.

-- Describe the problem consumers may encounter, what can or has occurred, and provide a brief description of the public health risk.
-- If there are other recalls related to this one, include those as well.

Tell the user what they should do with the affected product. For example, stop using it, return it, contact their doctor, etc.
Also, let them know when it was manufactured and distributed. Think of this as a short abstract. You need to be able to grab the public's attention in those first few seconds.
Remember, be concise and to the point.

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Next give them information to identify the affected product.

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This information should include, but is not limited to:

-- the name and quantity of each product
-- Any coded information on your product, such as catalog numbers, lot or batch numbers, National Health Related Items Code (also known as NHRIC) or any other information noted in this slide.
FDA understands that sometimes the list maybe too extensive for the Press Release.
If you're unable to include all of this information, let your customers know where they can go for more information. For example, direct them to a telephone number or a website. Please discuss this with your Recall Coordinator.

SLIDE 14
In this next section, we'll discuss how you can provide the public with information about the recall.

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Let the public know how you learned of the problem, and that the FDA has been notified.
Provide a brief explanation about what is known about the problem. Include any confirmed injuries or deaths, if they exist.
If no injuries or deaths were reported, include that information as well.

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In the next section, you will add information about how the product and information has been distributed.

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Inform the public of whom you notified, and how.
Let the user know what you want them to do if they have the affected product. For example, do they need to return it, or do they need to request a replacement device? This may also include software updates.

Also add where the product was distributed. This includes the types of outlets, for example hospitals or pharmacies; the states where the product was distributed and in urgent situations, consider issuing a press release that could be nationwide or to specific geographical areas only, for example the West Coast.

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And finally, provide them with a way to contact both you and the FDA.

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This contact information must include a telephone number. An 800 number is preferred. Also provide an email if available,
and provide a way to contact FDA directly
-- Either Online, where they can download a form to mail or fax,
and by providing the FDA toll free number which is shown on the slide.

SLIDE 20
Do not include the following material on your press release:

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

SLIDE 21
Remember, Medical Device Recall Press Releases should provide clear and concise information concerning the Recall Health Risk to users.
They should be Issued promptly, and you should always Contact your local District Office with your draft press release to discuss its content.

SLIDE 22
This slide provides some websites you may find useful and informative.

SLIDE 23
This slide provides additional websites that may also be helpful.

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We hope that this new template will be a helpful and useful mechanism for alerting your customers. If you have further questions regarding reporting requirements, contact your local FDA District Recall Coordinator, or refer to the other sources listed on this slide. Thank you for your time and attention!!