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Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C Draft Guidance for Industry and FDA Staff

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Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-3548.

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**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs**

1/17/2018

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**U.S. Department of Health and Human Services
Food and Drug Administration
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Recalls

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Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C¹ Draft Guidance for Industry and FDA Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this draft guidance as listed on the title page.

I. Introduction:

The purpose of this draft guidance is to assist and provide recommendations to industry and FDA staff regarding the use, content, and circumstances for issuance of public warnings and public notifications for firm-initiated or FDA-requested recalls under 21 CFR Part 7, Subpart C – Recalls (Including Product Corrections) – Draft Guidance on Policy, Procedures, and Industry Responsibilities. The draft guidance also discusses what information should be included in a public warning, as well as the parties responsible for issuing it. It represents FDA’s current thinking on public warning and notification of recalls under 21 CFR Part 7.

This draft guidance applies to voluntary recalls of products subject to FDA’s jurisdiction, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, any tobacco product intended for human use, and any item

¹ This draft guidance has been prepared by the Office of Strategic Planning and Operational Policy (OSPOP), in the Office of Regulatory Affairs (ORA), in cooperation with the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), the Center for Veterinary Medicine (CVM), the Center for Tobacco Products (CTP), and the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

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subject to a quarantine regulation under part 21 Part 1240. However, it does not apply to radiation emitting electronics which are governed by 21 CFR Part 1003 and 1004.

FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Terminology:

Recall

Recall means a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the Agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery. (21 CFR §7.3(g)).

Recall Determination

A recall determination is the assessment FDA makes in deciding that a firm's ongoing or completed removal or correction of a marketed violative product constitutes a recall as defined at 21 CFR § 7.3(g). A firm's characterization of its action is not determinative of whether FDA would designate the action as a recall. A firm's action constitutes a recall when it meets the definition of "recall" under 21 CFR § 7.3(g).

Recall Classification

Recall classification means the numerical designation, i.e., I, II, or III, assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled or considered for recall. (21 CFR §§ 7.3(m), 7.41(b)). The determination is made on the basis of the health hazard evaluation and in consideration of the factors provided at 21 CFR §7.41.

Public Warning

The purpose of a public warning under 21 CFR Part 7 is to alert the public that a product being recalled presents a serious health hazard. It is reserved for urgent situations where other means of preventing use of the recalled product appear inadequate. (21 CFR §7.42(b)(2)).² Public warnings under 21 CFR Part 7 can be disseminated through general or specialized news media, e.g., professional or trade press, and/or to specific segments of the population such as physicians, hospitals, etc. FDA may issue public warnings in a variety of forms, including, but not limited to, press releases, emails, and web and social media postings.

Public Notification of Recalls

FDA promptly makes available to the public in the weekly [FDA Enforcement Report](#) a descriptive listing of each new recall according to its classification, whether it was FDA-

² In addition to the public warning authority described in 21 CFR Part 7, the Agency has other authorities to disseminate information in an array of circumstances. Nothing in this draft guidance is meant to define, shape or limit those authorities in any way.

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requested or firm-initiated, and the specific action being taken by the recalling firm. (21 CFR § 7.50).

Confidential Commercial Information (CCI)

Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs. (21 CFR §20.61(b)).

III. Discussion:

FDA's policy is to evaluate the particular circumstances of each individual recall in determining whether a public warning is needed in accordance with 21 CFR §7.42(b)(2) as part of the recall strategy. FDA may issue a public warning or notification before formally classifying a recall under 21 CFR § 7.4. We note that due to the level of hazard associated with Class I recalls, FDA has generally issued, and/or sought issuance of, public warnings in Class I or potential Class I recalls unless specific circumstances indicate that one would not be beneficial to the public. FDA also recommends and/or issues public warnings for some urgent Class II recalls that, while not rising to Class I hazards, still present a serious hazard to health.³

Once FDA makes a recall determination, the recall is listed in the weekly [FDA Enforcement Report](#) in accordance with 21 CFR §7.50.

A. Public Warnings

1. Under what circumstances should firms issue public warnings?

Public warnings are for urgent situations to alert the public that a product being recalled presents a serious hazard to health, and where other means for preventing the use of a recalled product appear inadequate. For instance, public warnings may be appropriate for urgent recalls of prescription drugs or medical devices when retail level consignees cannot identify persons to whom the drug or device was dispensed. A public warning is also often needed when a recalled product has been widely distributed.

On the other hand, when recalled products have only been distributed to direct accounts⁴, and the recalling firm has records that show exactly where the product has gone, a prompt and initial oral communication to such accounts informing them of the recall may be adequate⁵ to prevent the use of a recalled product. This could be an instance where the product has only reached the wholesale level, such as a warehouse or distribution center, and has not been further distributed to the retail or consumer level.

³ See 21 CFR Part 7 and FDA's 2003 Guidance for Industry: Product Recalls, Including Removals and Corrections.

⁴ For internet purchases, the consumer level is considered a direct account. For these types of purchases prompt and oral communication may not be feasible, and thus distribution to the direct account in an internet transaction may warrant a public warning.

⁵ A letter or even email may not be considered adequate due to delays or lack of receipt of confirmation.

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FDA policy generally recommends public warning for recalls that are likely to be classified as, or have been classified as Class I recalls, unless specific circumstances indicate that the warning would not be beneficial to the public. Such circumstances could be where there is not adequate information to convey risk and appropriate actions, or when the product is limited to a small number of users that are easily identified and can be rapidly reached through targeted contact. Furthermore, different products might dictate different communication considerations. For instance, during a medical device recall, FDA may consider how patients respond to a public warning about a defective product without first having the benefit of consulting with their physician. In these and similar situations, public warnings may be more confusing than helpful.

FDA will continue to assess the need for public warnings for voluntary recalls of FDA-regulated products based on the particular circumstances of the individual recall. The following recalls present examples of serious hazards to health such that a public warning may be warranted:

- Recalls of food products initiated by a firm after receipt of consumer reports of illness or injury (including allergic reactions), for which there is an active outbreak associated with the product or its ingredients, or for which FDA has substantiated reports of illness or injury.
- Recalls of food products that are intended for or would more likely be consumed by vulnerable populations. Examples of vulnerable human populations include infants, toddlers, the elderly, pregnant women, and medically-compromised individuals, who may be more susceptible to foodborne hazards than healthy persons.
- Recalls of food products initiated because of manufacturing deviations where the consequences of the manufacturing deviations could have significant health impacts; e.g., under processed low-acid canned foods which could result in botulism if the product is consumed.
- Recalls of food products initiated because of microbiological pathogen findings (e.g., *Listeria monocytogenes*, *Salmonella*, etc.) in environmental testing where direct food manufacturing contact surfaces are found to be contaminated.
- Recalls of animal food products which may be contaminated with low levels of drugs or unsafe food additives. Examples include pet jerky treats contaminated with antibiotics, and cat food products containing propylene glycol.
- Recalls of medical devices which may malfunction and lead to incorrect dosing of drugs or blood volumes.
- Recalls of sterile injectable drug products with particulate matter.
- Recalls of drug products associated with reports of death.

FDA may issue or supplement a firm's public warning, among other actions, in the following situations: a firm refuses to issue its own public warning when recommended or requested by FDA, an ongoing recall or public warning is not prompt or effective, or FDA learns of a

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completed recall where new adverse events associated with the product are reported after completion of the recall. FDA will generally provide a timeframe for when the firm should issue a public warning based on the circumstances of the individual recall. While timeframes will vary depending on the recall, these firms should generally issue a public warning within 24 hours of FDA notifying the firm it believes a public warning is appropriate.

2. Who prepares public warnings?

FDA generally gives firms the first opportunity to prepare and issue public warnings during recalls. For instance, for firm-initiated recalls, recalling firms are expected to develop their own recall strategy. Recall strategy addresses, among other things, whether a public warning is needed and how it will be issued. In most cases FDA reviews and comments on the recall strategies, including any public warnings developed by firms (see 21 CFR §7.42(b)(2)). Firms should include any drafted public warning as part of their submission of the recall strategy to the extent that it does not delay strategy development or recall initiation.⁶ In other situations that warrant immediate warning, firms may choose to issue public warnings without FDA's review. FDA may supplement that warning with its own public statement, if necessary. When FDA believes that a public warning is appropriate and the recalling firm does not include one in its initial recall strategy, FDA will generally request one from the recalling firm.

In some situations, FDA may prepare and issue public warnings on its own initiative and in accordance with 21 CFR §7.42(b)(2). This may occur, for instance, when the public needs immediate warning concerning a product and the firm has not issued a public warning or a firm's public warning is deficient. FDA will ordinarily work with the recalling firm to ensure the factual accuracy of a public warning. However, FDA is not required to contact the firm before issuing a public warning or allow its review of the proposed statement.

If a firm issues a public warning that is deficient in any respect (see also section III.A.3 in this document), FDA may supplement or correct that warning with its own public warning. If a firm's public warning is not reasonably likely to be adequately received by the target audience, FDA may ask the firm to reissue its public warning and/or FDA may issue its own public warning. Additionally, FDA may publicly issue information that may address outstanding questions about the nature of the incident and/or the agency's actions.

3. What information should be contained in a public warning?

The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. As such, a public warning should include: a) information to help identify the recalled product including images, codes (e.g., lot number, expiration date, serial number, unique device identification (UDI) number), packaging information or brand names; b) the geographic areas and dates of distribution of the product; c) a thorough description of the product defect, health hazard involved and reason(s) for recall (e.g., product testing,

⁶ Firms are reminded that, under 21 CFR §7.42, they need not delay the initiation of a recall pending FDA's review of their recall strategy.

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environmental sampling, etc.); d) the name and contact information for the recalling firm; e) instructions to consumers or users; f) the number and nature of any illnesses/injuries/complaints associated with the product; and g) a description of common symptoms of any illness of concern. The headline of the public warning should include the brand name, type of product, and the hazard prompting the recall (e.g., “XYZ chocolate chip cookies recalled for potential Salmonella contamination.”).

In some cases, it may also be necessary to include the recalling firm’s supply-chain relationships in order to alert the public of the product being recalled. When possible, FDA encourages firms to provide specifics about firms it sold product to in order to help people better identify and avoid recalled product.⁷

What not to include

Public warnings should not contain content that detracts from or defeats the purpose of the warning. Brief and succinct warnings are generally better at informing consumers of a product hazard and helping consumers understand the importance of avoiding the product. On the other hand, messages that cloud or lengthen a warning may distract a consumer and should be avoided. Firms should not promote the qualities of the product being recalled, other products sold by the firm, or the firm in general, as part of a public warning. Phrases such as “an abundance of caution,” that can be seen as trying to minimize the hazard, should not be used, for example, when illnesses or injury have resulted, or when there are positive results for pathogens associated with the finished product or ingredients.

Deficient public warnings

A public warning may be considered deficient if, among other things, it does not adequately identify the recalled product, describe the health hazard involved, or identify relevant information about the product’s distribution. A public warning might also be considered deficient if, on the basis of FDA’s media monitoring, it is determined that the warning did not sufficiently reach the target audience (e.g., the firm’s release was not disseminated sufficiently by the news media; the firm’s warning for a nationally-distributed product was issued only to a regional audience; no Spanish translation was made available for a product largely used by Spanish-speaking populations). A factual statement in a firm’s public warning that FDA is unable to verify might also cause FDA to issue a separate public warning. FDA will take actions to correct or supplement deficient public warnings as described in this draft guidance. The agency encourages firms issuing public warnings to monitor media coverage and take further action to raise public awareness if media coverage is insufficient.

4. How are Public Warnings Distributed and Displayed?

⁷ FDA’s recall communications are intended to be as informative as possible within the scope of the agency’s authority for information disclosure. For example, depending on the circumstances, certain information such as supply-chain relationships and product distribution data may be CCI, which is generally protected from public disclosure. FDA’s regulations authorize the release of CCI, in relevant part, when necessary to effectuate a recall. (21 CFR §20.91).

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Firms and FDA can alert the public about a recall by various means, including issuing press releases to the media, sending emails to a listserv or subscription service, and posting on FDA and company websites or social media. All of these methods could be used to issue a public warning.

Issuing the Public Warning through a Press Release

It is critical that public warnings are distributed in a way that ensures that the information conveyed in the warning actually reaches the public. To this end, FDA is open to different vehicles of dissemination that best convey the information of the particular recall. Historically, FDA and industry have used general news media, as well as specialized news media, e.g., professional or trade press, among other means. When warranted, FDA recommends that firms use press release distribution services or other mechanisms that guarantee the information in the press release will be appropriately relayed to the public, e.g., through news media outlets. Part of a firm's responsibility to inform a consumer of a recalled product includes taking earnest efforts to ensure that the information is actually distributed.

Firms issuing public warnings through press releases should also consider the area of distribution of the recalled product. The distribution of the release should match the distribution of the product: if the product is available online or is distributed nationally, the public warning should also be available online and/or distributed nationwide. Similarly, if the product is only available in a regional market, and FDA and the firm are confident that no consumers from outside that region may have received it, the distribution of the public notification may be similarly targeted. If it is apparent that a significant percentage of consumers using the recalled product speak a language other than English, firms should consider having the public warning translated into that language and distributed via the appropriate distribution service.

Posting a Public Warning or Press Release on a firm or FDA Webpage

In many cases, a firm will announce a removal of an FDA regulated product from the market or correction⁸ through a press release or other public announcement prior to FDA reviewing and determining the action to be a recall. FDA may post the information in or the text of the announcement on [FDA.gov/recalls](https://www.fda.gov/recalls)⁹ if FDA believes the announcement is factually correct and beneficial to consumers.

FDA does not typically post a firm's announcement of an action that FDA believes will not be considered a recall. Further, not all recalls are posted on the [FDA.gov/recalls](https://www.fda.gov/recalls) page since not all recalls warrant a public warning and not all firms will issue a press release, depending on the circumstances. When FDA posts removal or correction information that has been publicized by a firm, we do so as a public service and it does not necessarily mean that the situation is urgent or that the product presents a serious hazard to health, such that it would be considered a "public warning" as the term is defined in this draft guidance document. Information on major product

⁸ A correction is a repair, modification, adjustment, relabeling, destruction or inspection (including patient monitoring) of a product without its physical removal to some other location. 21 CFR 7.3(h).

⁹ This webpage also provides links to various FDA Center webpages, where public warnings of recalls of products specific to that Center are also posted.

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recalls that FDA believes merit expanded coverage due to the impact they have on public health can be found at <https://www.fda.gov/Safety/Recalls/MajorProductRecalls/default.htm>. When a firm posts its public warning on its own webpage, it should ensure that the warning is prominently displayed and accessible from both its home page and a web search.

B. Public Notification of Recalls

FDA provides public access to information on recalls by posting a listing of recalls according to their classification in the [FDA Enforcement Report](#), whether they were requested by FDA or firm-initiated, and the specific action taken by the recalling firm.¹⁰ The FDA Enforcement Report is designed to provide a public listing of products in the marketplace that are being recalled. Unlike with public warnings, the recalls listed in the FDA Enforcement Report are not limited to urgent situations that present serious hazards to health and are not necessarily used to alert the public about the risk or hazard of a product under recall.

Information on all recalls will be provided in the FDA Enforcement Report, regardless of the level of the hazard. FDA will attempt to promptly post public notifications; however, delays might occur due to the timeliness of a firm's recall submission, the availability of facts, and other factors outside FDA's control. FDA may consider delaying public notification if necessary to avoid anxiety in certain consumers (e.g., when a patient needs to hear first from his doctor about a defective implanted medical device). FDA is not required to provide firms with an opportunity to review and comment on public notifications, but may consult with a firm to ensure factual accuracy or when otherwise warranted.

Public notifications of recalls will only be posted in the FDA Enforcement Report after FDA makes a determination that the action is a recall under 21 CFR §7.3(g). If the recall posted in the FDA Enforcement Report has not yet been classified, FDA will document the recall as not yet classified.

IV. References

We have placed the following references on display in the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of [insert date], we have verified the website addresses, but we are not responsible for any subsequent changes to websites after we announce the availability of this document in the **Federal Register**.

1. U.S. Food and Drug Administration. Guidance for Industry: Product Recalls, Including Removals and Corrections. Last updated 08/22/2014. Accessed 04/2017.
<https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>
2. U.S. Food and Drug Administration. "Recalls, Market Withdrawals, & Safety Alerts." Last updated 04/04/2017. Accessed 04/2017.
<https://www.fda.gov/Safety/Recalls/default.htm>

¹⁰ We note that, although they are not the subject of this draft guidance document, mandatory recalls are also listed in the enforcement report.

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3. U.S. Food and Drug Administration. “Industry Guidance for Recalls. Information on Recalls of FDA Regulated Products.” Last updated 08/15/2014. Accessed 04/2017.
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm>
4. U.S. Food and Drug Administration. Recalls, Corrections and Removals (Devices). Last updated 01/03/2017. Accessed 5/12/2017.
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm>