Using Electronic Means to Distribute Certain Product Information

Guidance for Industry [1]

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I. Introduction

This guidance is intended to describe the Food and Drug Administration's (FDA, we, or Agency) current thinking regarding the format and methods of dissemination and distribution of product information, including voluntary recall communications for FDA-regulated products and/or important drug safety information subject to 21 CFR §§ 7.49 and/or 200.5. This document provides guidance to persons who wish to use forms and formats of communication other than those specifically described in FDA's regulations, 21 CFR §§ 7.49 and 200.5, when conveying voluntary recall communications about FDA-regulated products and important drug safety information. This guidance also applies to those instances, not addressed in any regulation, where we recommend

that manufacturers and distributors voluntarily convey certain safety information about their products to members of the public. We encourage the use of electronic communications for conveying all such important product safety information.

FDA's guidance documents, including this guidance, 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. Background

The timely dissemination of communications about recalls of FDA-regulated products, important drug safety information, and other important product safety information is essential for the protection of the public health. We encourage manufacturers and distributors to provide such information in a timely manner to distributors, doctors, and others. Over the years, we have worked with manufacturers and distributors to promote the use of electronic methods of communication and encourage the use of innovative technologies to disseminate safety information, particularly when doing so can provide a public health benefit.

The use of e-mail and other electronic communications has dramatically changed how we and the public convey information. Electronic communications have a number of advantages over paper-based communications. They can significantly shorten the time between an event and the public's knowledge of the event. Rapid communication is especially important when the event involves product safety. E-mail and other electronic communications can be more efficient and more timely than regular or traditional mail. They involve considerably less cost to the sender than older, more traditional delivery services. Receipt or delivery can be automatically verified through various means such as a delivery or read receipt confirmation or other electronic receipt acknowledgement mechanisms. Any necessary followup (such as when receipt of the e-mail is not acknowledged in some fashion) also can be accomplished electronically. If receipt of the electronic communication is not acknowledged appropriately by the recipient (as determined by the sender) or the electronic communication is undeliverable, the sender can resort to more traditional notification methods or other means to ensure the communication is received.

FDA's regulation, 21 CFR § 7.49, addresses the purpose, implementation, and content of communications by a firm with each of its direct accounts concerning any recall. The regulation applies to FDA-regulated products including food, drugs, cosmetics, medical devices, animal drugs, and biologics. Published in 1978, this regulation was implemented before the Internet made e-mail communications commonplace. The purpose of a recall communication is to convey that a particular product is subject to a recall, that further distribution or use of the product should cease, and, if applicable, directly notify customers who received the product, and provide instructions for return. 21 CFR § 7.49(a). The regulation also states:

- A recall "can be accomplished by telegrams, mailgrams, or first class letters." 21 CFR § 7.49(b).
- The recall communication should be brief and to the point. It should explain the reason for the recall and the hazard involved, if any; clearly identify the product with size, lot numbers or other identifying information; and provide a means of contact. 21 CFR § 7.49(c).
- The recall communication should contain information on the "ready means for the recipient to report to the recalling firm whether it has any of the product." Examples given include mail or collect calls. 21 CFR § 7.49(c)(1)(v).
- If necessary, ". . . followup communications should be sent to those who fail to respond to the initial recall communication. 21 CFR § 7.49(c)(2).

Presently, industry and retail operations, similar to healthcare providers, are increasingly relying on electronic communications to receive information and conduct business operations. We are making it clear in this guidance that dissemination of voluntary recall information, any necessary followup, and the recipient acknowledgement and/or report to the recalling firm also can be accomplished under the regulation by e-mail and other electronic communication methods.

In 1967, before the advent of the Internet and the ease of electronic communications, we also implemented a regulation detailing the method we would use to send important drug information to healthcare providers. The regulation also asks that manufacturers and distributors use this same method for information they send to healthcare providers. Specifications for this method, in 21 CFR § 200.5, include the type of mail, envelope size and color, specific formatting, headings, and font size. The intent of this regulation, as stated in the provision, was to help ensure that "physicians and others responsible for patient care" would recognize the significance of the communication and read it, rather than discard it as junk mail or advertising from the manufacturer.

Many are now concerned that these important drug information communications sent to physicians and other health care providers are not reaching the intended audience in a timely manner or at all. Letters to health care providers often are screened by one or more "gatekeepers" and may not reach the intended recipients – the providers who need the drug information for treating patients. Gatekeepers often discard these mailings as "junk mail."

Over 819,000 physicians and surgeons, 58,000 veterinarians, 2.4 million nurses, 380,000 medical assistants, 232,000 pharmacists, and many other healthcare providers and facilities in the United States can benefit from the important drug information provided under 21 CFR § 200.5. As with the public, an increasing number of healthcare providers utilize e-mail and other electronic methods to receive information and to conduct business activities. Many healthcare providers have voluntarily signed up with services that provide electronic notifications of product and safety information. Electronic notification is a viable alternative to more traditional methods, particularly where the healthcare provider voluntarily provides an e-mail address, or other electronic address. In effect, the healthcare provider allows the sender to bypass spam filters and possible deletion of unsolicited communications. Despite the advantages of electronic communication, there are risks that e-mail

and other electronic communications can be used to disseminate false information. Senders often address these concerns by incorporating safeguards into their systems such as authentication and verification programs so recipients are assured of the identity of the sender. We are making clear in this guidance that manufacturers and distributors may disseminate the product and safety communications by e-mail or other electronic methods.

We have initiated a number of efforts to use electronic means to provide immediate and current agency updates to the public and to specific audiences. We provide website updates on bioterrorism, new product approvals, labeling changes, product recalls, and medical product safety information. We also provide free e-mail subscription services for subscribers to receive updates on FDA-regulated products. These subscription services can be accessed through our website at **http://www.fda.gov (http://www.fda.gov/)** and by visiting the webpage for the product area of interest. Many physicians and other healthcare providers have voluntarily signed up to receive these electronic notifications. To provide emerging safety information on FDA-regulated drug products, we launched the Drug Safety Initiative in February 2005. We designed this initiative to allow us to make established and newly emerging drug safety information available in an easily accessible format for healthcare providers, patients, and others. We also encourage manufacturers to provide drug safety information in a more accessible and timelier manner, such as through similar electronic communications.

In compliance with statutory initiatives, *e.g*. *Paperwork Reduction Act of 1995*, Pub. L. 104-13 (May 22, 1995) and *Government Paperwork Elimination Act*, Pub. L. 105-277, Title XVII (October 21, 1998), we have issued regulations and guidances providing for the electronic submission of information and forms, electronic signatures, and the retention of electronic records by regulated entities. Each of these efforts recognizes communications advances and acknowledges that industry, healthcare providers, and other professionals may use electronic means to comply with various FDA regulations.

III. Agency Position on Use of Electronic Communications

We interpret the provisions of 21 CFR §§ 7.49 and 200.5 to allow the use of e-mail and other electronic communication methods, such as fax or text messaging, to accomplish any recall notification or distribution of important safety information. Section 7.49(b) provides that, “A recall communication can be accomplished by telegrams, mailgrams, or first class letters….” Given the use of the term “can,” we read the three examples as being illustrative rather than the sole means of accomplishing recall communications.

As explained above, the provisions of 21 CFR § 7.49 for recall communications apply to FDA-regulated products.[2] We encourage manufacturers and others to make use of any current technology, including e-mail, to provide information under 21 CFR §§ 7.49 and/or 200.5. We also encourage the use of electronic communications for important safety information not addressed in any FDA regulation, including the communication of voluntary safety information on any FDA-

regulated product. We will consider e-mail and other electronic communication methods, such as fax, text messaging or other technological advances, to be appropriate, provided they accomplish the same objective (i.e., effective risk communication) of traditional delivery communications.

We expect that the means of communication chosen effectively convey the necessary information to the intended recipient. The provisions in 21 CFR § 7.49(a) and (c) include recommendations for the recall communication, content, and recipient response. These can be modified as needed for e-mail and other electronic communications. The specific provisions are as follows:

(a) General. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall.

(2) That further distribution or use of any remaining product should cease immediately.

(3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.

(4) Instructions regarding what to do with the product.

* * * * *

(c) Contents.

(1) A recall communication should be written in accordance with the following guidelines:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) Explain concisely the reason for the recall and the hazard involved, if any;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, followup communications should be sent to those who fail to respond to the initial recall communication.

We note that formatting and heading specifications for letters and envelopes in the current regulations, 21 CFR § 7.49(b) and 21 CFR § 200.5, are generally inapplicable to e-mail and electronic communications. We are not defining a specific format for e-mail or other electronic communications. To the extent possible, however, such e-mail and other electronic communications should follow any specifications that are feasible (such as marking the e-mail "URGENT" for appropriate recalls under 21 CFR § 7.49(b)). The provisions of 21 CFR § 200.5 are more detailed concerning the formatting, lettering, and statements on a communication's envelope. We recommend that these provisions be followed to the extent possible for e-mail and other electronic communications. For example, the envelope statements can be included in the body of the e-mail message or as a PDF attachment. Consistent with this regulation, the e-mail or other electronic communication also should be “distinctive in appearance so that it will be promptly recognized and read.” For example, the subject line of the communication should include a signal of its importance, similar to the bold headers in mailings, together with the name of the drug product. The body of the communication should be concise, clear, and identify the consequences if the information is not followed or used in the medical treatment of patients. The communications should not be promotional or contain links to other promotional materials.

IV. Other Relevant Agency Guidances

In November 2003, we published a *Guidance For Industry: Product Recalls, Including Removals and Corrections* (Recalls Guidance) that was intended to assist in handling all aspects of a product recall, including the documentation and information we would use to evaluate, monitor, and audit a recall. The Recalls Guidance states that a company's recall strategy should “indicate the method of notification.” The examples of a method are “mail, phone, facsimile, e-mail.” Thus, under the Recalls Guidance, e-mail is considered to be a “written communication.” In evaluating the effectiveness of the recall, the recall check should indicate that the recall notification was received, read, understood, and/or instructions followed, and reached the appropriate level in the distribution chain. The Recalls Guidance and the Regulatory Procedures Manual (RPM), Chapter 7 (revised June 14, 2005),[3] elaborate on the critical information that is to be included in a notification. The information is designed to help companies and FDA ensure the effectiveness of the recall.

In August 2003, we published a *Guidance for Industry: Part 11, Electronic Records: Electronic Signatures – Scope and Application* (Part 11 Guidance) to provide guidance for FDA's interpretation of final part 11 regulations issued in 1997. The Part 11 Guidance was intended to assist entities that maintained and/or submitted records required under FDA regulations in an electronic format. The Part 11 Guidance details our intent to interpret the scope of part 11 narrowly, defines part 11 records, and explains our enforcement discretion in relation to copies of such records and record retention. The Part 11 Guidance also notes that for records maintained in an

electronic format, but that are not subject to underlying regulations, part 11 would not apply. The Part 11 Guidance is useful for determining if a record is considered a part 11 record and thus subject to part 11 and the enforcement discretion outlined in the guidance. The relevancy of the Part 11 Guidance and any part 11 regulations will depend on an individual company's decisions regarding its applicable records.

This guidance document is intended to supplement the information contained in the Recalls Guidance and the RPM, Chapter 7, to clarify that e-mail and other electronic communications are acceptable as methods of notification for voluntary recall communications and distribution of important drug safety information. We will evaluate the use of e-mail and other electronic communications, such as faxes, text messaging, or other technological advances, for the effectiveness of the recall communication similar to traditional delivery methods. Proof of receipt through various means such as delivery or read receipt confirmation and other electronic receipt acknowledgement mechanisms will assist in determining the effectiveness of the recall communications. For voluntary recalls, such communications should be received, read, understood, and/or instructions followed, and reach the appropriate level in the distribution chain as other forms of recall communications. Those who send voluntary recall communications should provide documentation of the recall communications and the effectiveness of the recall in accordance with our regulations or as described in existing guidances.

Footnotes:

[1] This guidance has been prepared by the Office of Policy in the Office of Commissioner at the Food and Drug Administration (FDA).

[2]We note that this guidance does not interpret the provisions of 21 CFR § 810.15 for device products, or of 21 CFR § 1271.440 for human cell, tissue, and cellular and tissue-based products (HCT/Ps). For mandatory recalls of devices, device manufacturers must reference their specific recall order and 21 CFR § 810.15. For mandatory recalls of HCT/Ps, manufacturers must reference their specific recall order and 21 CFR § 1271.440. This guidance also does not interpret the mandatory recall communications for infant formula at 21 CFR §§ 107.230 and 107.240 nor the recall provisions in section 351(d)(1) of the Public Health Service Act (42 USC 262(d)(1)).

[3]The Regulatory Procedures Manual is a reference manual for FDA personnel. It provides FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters.

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