

GUIDANCE FOR INDUSTRY

Using Electronic Means to Distribute Certain Product Information

DRAFT GUIDANCE

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Guidance for Industry¹ Using Electronic Means to Distribute Certain Product Information

This draft guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, please contact the appropriate FDA staff.

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 alternative 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

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

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37 protection of the public health. We have encouraged manufacturers to provide such information
38 in a timely manner to distributors, doctors, and others. Over the years, we have worked with
39 manufacturers to promote the use of electronic methods of communication and encourage the use
40 of innovative technologies to disseminate safety information, particularly those that provide a
41 public health benefit.

42

43 The use of e-mail and other electronic communications has dramatically changed how we and
44 the public convey information. Electronic communications have a number of advantages over
45 paper-based communications. They can significantly shorten the time between an event and the
46 public's knowledge of the event. When the event involves product safety, it is even more
47 important that accurate safety information be transmitted rapidly. E-mail and other electronic
48 communications are generally considered more efficient and more timely than regular or
49 traditional mail. These communications involve considerably less cost to the sender than older,
50 more traditional delivery services. Verification of receipt or delivery is less expensive and can
51 be automatically accomplished. Any necessary followup (such as when receipt of the e-mail is
52 not acknowledged) also can be accomplished electronically. If receipt is never acknowledged,
53 the sender can resort to more traditional methods of notification.

54

55 FDA regulations, 21 CFR § 7.49, address the purpose, implementation, and content of
56 communications by a firm with each of its direct accounts concerning any recall. The regulation
57 applies to FDA regulated products including food, drugs, cosmetics, medical devices, animal
58 drugs, and biologics. Published in 1978, this regulation was implemented before the Internet
59 made e-mail communications commonplace. The purpose of a recall communication is to
60 convey that a particular product is subject to a recall, that further distribution of the product
61 should cease, and, if applicable, directly notify customers who received the product, and provide
62 instructions for return. 21 CFR § 7.49(a). The regulation states that a recall "can be
63 accomplished by telegrams, mailgrams, or first class letters." 21 CFR § 7.49(b). The recall
64 communication should be brief and to the point explaining the reason for the recall and the
65 hazard involved, if any; clearly identify the product with size, lot numbers or other identifying
66 information; and provide a means of contact. 21 CFR § 7.49(c). The recall communication
67 should also contain information on the "ready means for the recipient to report to the recalling
68 firm whether it has any of the product." 21 CFR § 7.49(c)(v). The examples include mail or
69 collect calls. Presently, however, industry and retail operations, similar to healthcare
70 professionals, are increasingly relying on electronic communications to receive information and
71 conduct business operations. We are making it clear in this guidance that dissemination of
72 voluntary recall information can also be accomplished under the regulation by e-mail and other
73 electronic communication methods.

74

75 In 1967, before the advent of the Internet and the ease of electronic communications, we also
76 implemented a regulation detailing the method we would use to send important drug information
77 to healthcare providers. The regulation also asks that manufacturers and distributors use this
78 same method for information they send to healthcare providers. Specifications for this method in

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79 21 CFR § 200.5 include the type of mail, envelope size and color, specific formatting, headings,
80 and font size. The intent of this regulation, as stated in the provision, was to help ensure that
81 “physicians and others responsible for patient care” would recognize the significance of the
82 communication and read it, rather than discard it as junk mail or advertising from the
83 manufacturer.

84
85 Many are now concerned that these important drug information communications sent to
86 physicians and other health care providers are not reaching the intended audience and/or not
87 reaching them in a timely manner. Letters to health care professionals often are first seen by one
88 or more “gatekeepers” and may not reach the intended recipients – the providers who need the
89 drug information for treating patients. Gatekeepers often discard these mailings as “junk mail.”
90

91 There are over approximately 819,000 physicians and surgeons, 58,000 veterinarians, 2.4 million
92 nurses, 380,000 medical assistants, 232,000 pharmacists, and many other healthcare providers
93 and facilities in the United States who can benefit from the important drug information provided
94 under 21 CFR § 200.5. As with the public, an increasing number of healthcare providers utilize
95 e-mail and other electronic methods to receive information and to conduct business activities.
96 Many healthcare providers have voluntarily signed up with services that provide electronic
97 notifications of product and safety information. Electronic notification is a viable alternative to
98 more traditional methods, particularly since the healthcare provider voluntarily provides an e-
99 mail address, or other electronic address, thus avoiding spam filters and deletion of unwanted
100 communications. We are making clear in this guidance that manufacturers may also disseminate
101 the communications by e-mail or other electronic methods.
102

103 We have initiated a number of efforts designed to provide immediate and current agency updates
104 to the public and to specific audiences through electronic means. We provide Web site updates
105 on bioterrorism, new product approvals, labeling changes, product recalls, and drug safety
106 information. We also provide free e-mail subscription services for subscribers to receive updates
107 on FDA regulated products. Many physicians and other healthcare providers have voluntarily
108 signed up to receive these electronic notifications. To provide emerging safety information on
109 FDA regulated drug products, we launched the Drug Safety Initiative in February 2005. The
110 initiative is designed to allow us to make established and newly emerging drug safety
111 information available in an easily accessible format for healthcare professionals, patients, and
112 others. We also encourage manufacturers to provide drug safety information in a more
113 accessible and more timely manner, such as through similar electronic communications.
114

115 In compliance with statutory initiatives, *e.g.* *Paperwork Reduction Act of 1995*, Pub. L. 104-13
116 (May 22, 1995) and *Government Paperwork Elimination Act*, Pub. L. 105-277, Title XVII
117 (October 21, 1998), we have issued regulations and guidances providing for the electronic
118 submission of information and forms, electronic signatures, and the retention of electronic
119 records by regulated entities. Each of these efforts has recognized communications advances and

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120 acknowledged that industry and other professionals are able to use electronic means to comply
121 with various FDA regulations.

122
123 **III. Agency Position on Use of Electronic Communications**
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125 We interpret the provisions of 21 CFR §§ 7.49 and 200.5 to allow the use of e-mail and other
126 electronic communication methods, such as fax or text messaging, to accomplish any recall
127 notification or distribution of important safety information. Section 7.49(b) provides that, “A
128 recall communication can be accomplished by telegrams, mailgrams, or first class letters....”
129 Given the use of the term “can,” we read the three examples as being illustrative rather than the
130 sole means of accomplishing recall communications.

131
132 As explained above, the provisions of 21 CFR § 7.49 for recall communications apply to FDA
133 regulated products.² We encourage manufacturers and others to make use of current technology,
134 including e-mail, to provide information under 21 CFR §§ 7.49 and/or 200.5. We also encourage
135 the use of electronic communications for important safety information not addressed in any FDA
136 regulation. We will consider e-mail and other electronic communication methods, such as fax or
137 text messaging, to be appropriate, provided they accomplish the same objective (i.e. effective
138 risk communication) of traditional delivery communications.

139
140 We expect that any communications effectively convey the necessary information to the intended
141 recipient. The provisions in 21 CFR § 7.49(a) and (c) include recommendations for the recall
142 communication and content. These can be modified for e-mail and other electronic
143 communications to the extent necessary. The specific provisions are as follows:

144
145 (a) General. A recalling firm is responsible for promptly notifying each of its affected
146 direct accounts about the recall. The format, content, and extent of a recall
147 communication should be commensurate with the hazard of the product being recalled
148 and the strategy developed for that recall. In general terms, the purpose of a recall
149 communication is to convey:

- 150 (1) That the product in question is subject to a recall.
151 (2) That further distribution or use of any remaining product should cease immediately.
152 (3) Where appropriate, that the direct account should in turn notify its customers who
153 received the product about the recall.
154 (4) Instructions regarding what to do with the product.

155 * * * * *

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)).

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- 156 (c) Contents. (1) A recall communication should be written in accordance with the
157 following guidelines:
- 158 (i) Be brief and to the point;
 - 159 (ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any
160 other pertinent descriptive information to enable accurate and immediate identification of
161 the product;
 - 162 (iii) Explain concisely the reason for the recall and the hazard involved, if any;
 - 163 (iv) Provide specific instructions on what should be done with respect to the recalled
164 products; and
 - 165 (v) Provide a ready means for the recipient of the communication to report to the
166 recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-
167 addressed postcard or by allowing the recipient to place a collect call to the recalling
168 firm.
- 169 (2) The recall communication should not contain irrelevant qualifications, promotional
170 materials, or any other statement that may detract from the message. Where necessary,
171 followup communications should be sent to those who fail to respond to the initial recall
172 communication.

173
174 We note that formatting and heading specifications for letters and envelopes in the current
175 regulations, 21 CFR § 7.49(b) and 21 CFR § 200.5 are generally inapplicable to e-mail and
176 electronic communications. To the extent possible, however, such e-mail and other electronic
177 communications should follow any specifications that might apply (such as marking the e-mail
178 “URGENT” for appropriate recalls under 21 CFR § 7.49(b)). The provisions of 21 CFR § 200.5
179 are more detailed concerning the formatting, lettering, and statements on a communication’s
180 envelope. We request that these provisions be followed to the extent possible for e-mail and
181 other electronic communications. For example, the envelope statements can be included in the
182 body of the e-mail message. Under this regulation, the e-mail or other electronic communication
183 should also be “distinctive in appearance so that it will be promptly recognized and read.” For
184 example, the subject line of the communication should include a signal of its importance, similar
185 to the bold headers in mailings, together with the name of the drug product. The body of the
186 communication should be concise, clear, and identify the consequences if the information is not
187 followed or used in the medical treatment of patients. The communications should not be
188 promotional or contain links to other promotional materials.

189
190 **IV. Other Relevant Agency Guidances**

191
192 In November 2003, we published a *Guidance For Industry: Product Recalls, Including Removals*
193 *and Corrections* (Recalls Guidance) that was intended to assist in handling all aspects of a
194 product recall, including the documentation and information we would use to evaluate, monitor,
195 and audit a recall. The Recalls Guidance states that a company’s recall strategy should “indicate
196 the method of notification.” The examples of a method are “mail, phone, facsimile, e-mail.”
197 Thus, under the Recalls Guidance, e-mail is considered to be a “written communication.” In

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198 evaluating the effectiveness of the recall, the recall check should indicate that the recall
199 notification was received, read, understood, and/or instructions followed, and reached the
200 appropriate level in the distribution chain. The Recalls Guidance and the Regulatory Procedures
201 Manual (RPM), Chapter 7 (revised June 14, 2005),³ elaborate on the critical information that is
202 to be included in a notification. The information is designed to help companies and FDA ensure
203 the effectiveness of the recall.

204
205 In August 2003, we published a *Guidance for Industry: Part 11, Electronic Records: Electronic*
206 *Signatures – Scope and Application* (Part 11 Guidance) to provide guidance for FDA’s
207 interpretation of final part 11 regulations issued in 1997. The Part 11 Guidance was intended to
208 assist entities that maintained and/or submitted records required under FDA regulations in an
209 electronic format. The Part 11 Guidance details our intent to interpret the scope of part 11
210 narrowly, defines part 11 records, and explains our enforcement discretion in relation to copies
211 of such records and record retention. The Part 11 Guidance also notes that for records
212 maintained in an electronic format, but that are not subject to underlying regulations, part 11
213 would not apply. The Part 11 Guidance is useful for determining if a record is considered a part
214 11 record and thus subject to part 11 and the enforcement discretion outlined in the guidance.
215 The relevancy of the Part 11 Guidance will depend on the individual company’s decisions
216 regarding its applicable records.

217
218 This guidance document is intended to supplement the information contained in the Recalls
219 Guidance and the RPM, Chapter 7, to clarify that e-mail and other electronic communications are
220 acceptable as methods of notification for voluntary recall communications and distribution of
221 important drug safety information. We will evaluate the use of e-mail and other electronic
222 communications for the effectiveness of the recall communication similar to traditional delivery
223 methods. For voluntary recalls, such communications should be received, read, understood,
224 and/or instructions followed, and reach the appropriate level in the distribution chain as other
225 forms of recall communications. Those who send voluntary recall communications should
226 provide documentation of the recall communications and the effectiveness of the recall in
227 accordance with our regulations or as described in existing guidances.

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.