

# **GUIDANCE FOR INDUSTRY**

## **Using Electronic Means to Distribute Certain Product Information**

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of The Commissioner, Office of Policy  
March 2006**

2005D-0385

GDL 2

1 **GUIDANCE FOR INDUSTRY**

2  
3 **Using Electronic Means to Distribute**  
4 **Certain Product Information**

5  
6  
7  
8  
9  
10 Additional copies are available from:  
11 Office of Policy, Office of the Commissioner  
12 Food and Drug Administration  
13 5600 Fishers Lane  
14 Rockville, MD 20857  
15 (301) 827-3360  
16 <http://www.fda.gov/>  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26

27  
28 **U.S. Department of Health and Human Services**  
29 **Food and Drug Administration**  
30 **Office of The Commissioner, Office of Policy**  
31 **March 2006**  
32

Contains Nonbinding Recommendations

**Guidance for Industry<sup>1</sup>  
Using Electronic Means to Distribute  
Certain Product Information**

This 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 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.

<sup>1</sup> This guidance has been prepared by the Office of Policy in the Office of Commissioner at the Food and Drug Administration.

## Contains Nonbinding Recommendations

72 The use of e-mail and other electronic communications has dramatically changed how we and  
73 the public convey information. Electronic communications have a number of advantages over  
74 paper-based communications. They can significantly shorten the time between an event and the  
75 public's knowledge of the event. Rapid communication is especially important when the event  
76 involves product safety. E-mail and other electronic communications can be more efficient and  
77 more timely than regular or traditional mail. They involve considerably less cost to the sender  
78 than older, more traditional delivery services. Receipt or delivery can be automatically verified  
79 through various means such as a delivery or read -receipt confirmation or other electronic receipt  
80 acknowledgement mechanisms. Any necessary followup (such as when receipt of the e-mail is  
81 not acknowledged in some fashion) also can be accomplished electronically. If receipt of the  
82 electronic communication is not acknowledged appropriately by the recipient (as determined by  
83 the sender) or the electronic communication is undeliverable, the sender can resort to more  
84 traditional notification methods or other means to ensure the communication is received.  
85

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

- 94 ■ A recall "can be accomplished by telegrams, mailgrams, or first class letters." 21 CFR §  
95 7.49(b).
- 96 ■ The recall communication should be brief and to the point. It should explain the reason  
97 for the recall and the hazard involved, if any; clearly identify the product with size, lot  
98 numbers or other identifying information; and provide a means of contact. 21 CFR §  
99 7.49(c).
- 100 ■ The recall communication should contain information on the "ready means for the  
101 recipient to report to the recalling firm whether it has any of the product." Examples  
102 given include mail or collect calls. 21 CFR § 7.49(c)(1)(v).
- 103 ■ If necessary, ". . . followup communications should be sent to those who fail to respond  
104 to the initial recall communication. 21 CFR § 7.49(c)(2).

105 Presently, industry and retail operations, similar to healthcare providers, are increasingly relying  
106 on electronic communications to receive information and conduct business operations. We are  
107 making it clear in this guidance that dissemination of voluntary recall information, any necessary  
108 followup, and the recipient acknowledgement and/or report to the recalling firm also can be  
109 accomplished under the regulation by e-mail and other electronic communication methods.  
110

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

## Contains Nonbinding Recommendations

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

120

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

126

127 Over 819,000 physicians and surgeons, 58,000 veterinarians, 2.4 million nurses, 380,000 medical  
128 assistants, 232,000 pharmacists, and many other healthcare providers and facilities in the United  
129 States can benefit from the important drug information provided under 21 CFR § 200.5. As with  
130 the public, an increasing number of healthcare providers utilize e-mail and other electronic  
131 methods to receive information and to conduct business activities. Many healthcare providers  
132 have voluntarily signed up with services that provide electronic notifications of product and  
133 safety information. Electronic notification is a viable alternative to more traditional methods,  
134 particularly where the healthcare provider voluntarily provides an e-mail address, or other  
135 electronic address. In effect, the healthcare provider allows the sender to bypass spam filters and  
136 possible deletion of unsolicited communications. Despite the advantages of electronic  
137 communication, there are risks that e-mail and other electronic communications can be used to  
138 disseminate false information. Senders often address these concerns by incorporating safeguards  
139 into their systems such as authentication and verification programs so recipients are assured of  
140 the identity of the sender. We are making clear in this guidance that manufacturers and  
141 distributors may disseminate the product and safety communications by e-mail or other  
142 electronic methods.

143

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

157

## Contains Nonbinding Recommendations

158 In compliance with statutory initiatives, *e.g. Paperwork Reduction Act of 1995*, Pub. L. 104-13  
159 (May 22, 1995) and *Government Paperwork Elimination Act*, Pub. L. 105-277, Title XVII  
160 (October 21, 1998), we have issued regulations and guidances providing for the electronic  
161 submission of information and forms, electronic signatures, and the retention of electronic  
162 records by regulated entities. Each of these efforts recognizes communications advances and  
163 acknowledges that industry, healthcare providers, and other professionals may use electronic  
164 means to comply with various FDA regulations.  
165

### 166 **III. Agency Position on Use of Electronic Communications**

167  
168 We interpret the provisions of 21 CFR §§ 7.49 and 200.5 to allow the use of e-mail and other  
169 electronic communication methods, such as fax or text messaging, to accomplish any recall  
170 notification or distribution of important safety information. Section 7.49(b) provides that, “A  
171 recall communication can be accomplished by telegrams, mailgrams, or first class letters....”  
172 Given the use of the term “can,” we read the three examples as being illustrative rather than the  
173 sole means of accomplishing recall communications.  
174

175 As explained above, the provisions of 21 CFR § 7.49 for recall communications apply to FDA-  
176 regulated products.<sup>2</sup> We encourage manufacturers and others to make use of any current  
177 technology, including e-mail, to provide information under 21 CFR §§ 7.49 and/or 200.5. We  
178 also encourage the use of electronic communications for important safety information not  
179 addressed in any FDA regulation, including the communication of voluntary safety information  
180 on any FDA-regulated product. We will consider e-mail and other electronic communication  
181 methods, such as fax, text messaging or other technological advances, to be appropriate,  
182 provided they accomplish the same objective (i.e., effective risk communication) of traditional  
183 delivery communications.  
184

185 We expect that the means of communication chosen effectively convey the necessary  
186 information to the intended recipient. The provisions in 21 CFR § 7.49(a) and (c) include  
187 recommendations for the recall communication, content, and recipient response. These can be  
188 modified as needed for e-mail and other electronic communications. The specific provisions are  
189 as follows:  
190

191 (a) General. A recalling firm is responsible for promptly notifying each of its affected  
192 direct accounts about the recall. The format, content, and extent of a recall  
193 communication should be commensurate with the hazard of the product being recalled

---

<sup>2</sup> 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)).

## Contains Nonbinding Recommendations

194 and the strategy developed for that recall. In general terms, the purpose of a recall  
195 communication is to convey:

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

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

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

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

201 \* \* \* \* \*

202 (c) Contents. (1) A recall communication should be written in accordance with the  
203 following guidelines:

204 (i) Be brief and to the point;

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

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

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

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

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

219  
220 We note that formatting and heading specifications for letters and envelopes in the current  
221 regulations, 21 CFR § 7.49(b) and 21 CFR § 200.5, are generally inapplicable to e-mail and  
222 electronic communications. We are not defining a specific format for e-mail or other electronic  
223 communications. To the extent possible, however, such e-mail and other electronic  
224 communications should follow any specifications that are feasible (such as marking the e-mail  
225 "URGENT" for appropriate recalls under 21 CFR § 7.49(b)). The provisions of 21 CFR § 200.5  
226 are more detailed concerning the formatting, lettering, and statements on a communication's  
227 envelope. We recommend that these provisions be followed to the extent possible for e-mail and  
228 other electronic communications. For example, the envelope statements can be included in the  
229 body of the e-mail message or as a PDF attachment. Consistent with this regulation, the e-mail  
230 or other electronic communication also should be "distinctive in appearance so that it will be  
231 promptly recognized and read." For example, the subject line of the communication should  
232 include a signal of its importance, similar to the bold headers in mailings, together with the name  
233 of the drug product. The body of the communication should be concise, clear, and identify the  
234 consequences if the information is not followed or used in the medical treatment of patients. The  
235 communications should not be promotional or contain links to other promotional materials.  
236

## Contains Nonbinding Recommendations

### 237 IV. Other Relevant Agency Guidances 238

239 In November 2003, we published a *Guidance For Industry: Product Recalls, Including Removals*  
240 *and Corrections* (Recalls Guidance) that was intended to assist in handling all aspects of a  
241 product recall, including the documentation and information we would use to evaluate, monitor,  
242 and audit a recall. The Recalls Guidance states that a company's recall strategy should "indicate  
243 the method of notification." The examples of a method are "mail, phone, facsimile, e-mail."  
244 Thus, under the Recalls Guidance, e-mail is considered to be a "written communication." In  
245 evaluating the effectiveness of the recall, the recall check should indicate that the recall  
246 notification was received, read, understood, and/or instructions followed, and reached the  
247 appropriate level in the distribution chain. The Recalls Guidance and the Regulatory Procedures  
248 Manual (RPM), Chapter 7 (revised June 14, 2005),<sup>3</sup> elaborate on the critical information that is  
249 to be included in a notification. The information is designed to help companies and FDA ensure  
250 the effectiveness of the recall.  
251

252 In August 2003, we published a *Guidance for Industry: Part 11, Electronic Records: Electronic*  
253 *Signatures – Scope and Application* (Part 11 Guidance) to provide guidance for FDA's  
254 interpretation of final part 11 regulations issued in 1997. The Part 11 Guidance was intended to  
255 assist entities that maintained and/or submitted records required under FDA regulations in an  
256 electronic format. The Part 11 Guidance details our intent to interpret the scope of part 11  
257 narrowly, defines part 11 records, and explains our enforcement discretion in relation to copies  
258 of such records and record retention. The Part 11 Guidance also notes that for records  
259 maintained in an electronic format, but that are not subject to underlying regulations, part 11  
260 would not apply. The Part 11 Guidance is useful for determining if a record is considered a part  
261 11 record and thus subject to part 11 and the enforcement discretion outlined in the guidance.  
262 The relevancy of the Part 11 Guidance and any part 11 regulations will depend on an individual  
263 company's decisions regarding its applicable records.  
264

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

---

<sup>3</sup> 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.

**Contains Nonbinding Recommendations**

276 should provide documentation of the recall communications and the effectiveness of the recall in  
277 accordance with our regulations or as described in existing guidances.  
278