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Guidance for Industry Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

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Item Type	Preprint
Authors	Food and Drug Administration (FDA)
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Download date	2026-07-06 10:02:08
Link to Item	http://hdl.handle.net/20.500.12424/216126

Guidance for Industry

Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)**

**January 2014
Advertising**

Guidance for Industry

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1 Fulfilling Regulatory Requirements for Postmarketing Submissions of
2 Interactive Promotional Media for Prescription Human and Animal
3 Drugs and Biologics
4
5

6
7 This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s or
8 Agency’s) current thinking on this topic. It does not create or confer any rights for or on any person and
9 does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies
10 the requirements of the applicable statutes and regulations. If you want to discuss an alternative
11 approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the
12 appropriate FDA staff, call the appropriate number listed on the title page of this guidance.
13

14
15
16 **I. INTRODUCTION**
17

18 This draft guidance is intended to describe FDA’s current thinking about how manufacturers, packers,
19 and distributors (firms), that may either be the applicant or acting on behalf of the applicant, of
20 prescription human and animal drug and biological products (drugs) can fulfill regulatory requirements
21 for postmarketing submissions¹ of interactive promotional media for their FDA-approved products.^{2,3}
22 For the purposes of this guidance, the phrase *interactive promotional media* includes modern tools and
23 technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs,
24 social networking sites, online communities, and live podcasts) that firms use to promote their drugs.
25 Although some interactive promotional media are substantially similar in presentation and content to
26 certain traditional promotional media, such as print media, FDA recognizes that in other cases they
27 possess certain unique technological features and offer novel presentation and content features. This draft
28 guidance describes FDA’s current thinking on what the Agency considers to be interactive promotional
29 media and outlines the considerations taken into account in determining if product communications using
30 interactive technologies are subject to FDA’s postmarketing submission requirements. Furthermore, this
31 draft guidance provides FDA’s recommendations for how firms can fulfill the regulatory requirement to
32 submit postmarketing promotional materials to the FDA in a practical manner to address the potential

¹ 21 CFR 314.81(b)(3)(i); 21 CFR 601.12(f)(4); and 21 CFR 514.80(b)(5)(ii). See Section III for a detailed description of these postmarketing submission requirements.

² This draft guidance has been prepared by the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research (CBER) and the Center for Veterinary Medicine (CVM).

³ The recommendations in this draft guidance also apply to biological products that are approved for marketing under section 351 of the Public Health Service Act (PHS Act). Because each biological product also meets the definition of “drug” or “device” under the Federal Food, Drug, and Cosmetic Act (FD&C Act), it is also subject to provisions of the FD&C Act applicable to drugs or devices, as well as the regulations implementing these provisions, except that a biological product licensed under section 351 of the PHS Act is not required to have an approved new drug application under section 505 of the FD&C Act (21 U.S.C. 355). See PHS Act section 351(j), (42 U.S.C. 262(j)). The recommendations in this draft guidance do not apply to veterinary biological products regulated under the Virus-Serum-Toxin Act (21 U.S.C. 151, et seq.) by the U.S. Department of Agriculture.

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33 volume of real-time information that is continuously posted and shared through various interactive
34 promotional media platforms.

35
36 The organization of the draft guidance is as follows: after some background information regarding
37 postmarketing submission requirements (Section II), a brief legal overview of statutory and regulatory
38 requirements for labeling and advertising is presented, including postmarketing submission requirements
39 (III). Then, considerations related to submission of interactive promotional media are discussed with
40 some illustrative examples (IV), and, finally, FDA’s recommendations for submitting such promotional
41 materials are provided (V).

42
43 FDA’s guidance documents, including this draft guidance, do not establish legally enforceable rights or
44 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be
45 viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use
46 of the word *should* in Agency guidances means that something is suggested or recommended, but not
47 required.

48 **II. BACKGROUND**

49
50
51 FDA’s regulation of prescription drug product promotion extends both to promotional activities that are
52 carried out by the firm itself, and to promotion conducted on the firm’s behalf. In determining whether
53 the firm is accountable for a communication about its product(s), the Agency considers whether the firm
54 or anyone acting on its behalf is influencing or controlling the product promotional activity or
55 communication in whole or part. Firms may have a variety of options for how much control they exert
56 over activities that utilize interactive promotional media, regardless of whether the promotional activity
57 occurs on firm-sponsored or third-party venues. For example, a firm may promote its products through
58 product websites, discussion boards, chat rooms, or other public electronic forums that it maintains and
59 over which it has full control. In addition, third-party sites (i.e., websites and other venues that are either
60 entirely independent of a firm’s control and influence, or not fully controlled by a firm) may promote a
61 firm’s products.

62
63 As part of the postmarketing reporting requirements under the Federal Food, Drug, and Cosmetic Act
64 (FD&C Act), application holders are required to submit all promotional labeling and advertising pieces at
65 the time of initial dissemination of the labeling and at the time of initial publication of the advertisement
66 for a drug. However, for some interactive promotional media, submission “at the time of initial
67 dissemination” may pose a challenge for firms, particularly when these media communicate information
68 that is displayed in real time. While “at the time of initial dissemination” does not refer to submissions on
69 a weekly, monthly, or other routine schedule, FDA intends to exercise its enforcement discretion under
70 certain circumstances due to the high volume of information that may be posted within short periods of
71 time using interactive promotional media that allow for real-time communications. If a firm submits
72 interactive promotional media in the manner described in this draft guidance, FDA intends to exercise
73 enforcement discretion regarding the regulatory requirements for postmarketing submissions related to
74 promotional labeling and advertising.

75 **III. LEGAL OVERVIEW OF STATUTORY AND REGULATORY REQUIREMENTS FOR LABELING AND ADVERTISING**

76
77
78
79 Under the FD&C Act, the Agency has responsibility for regulating the manufacture, sale, and distribution
80 of drugs in the United States. This authority includes oversight of the labeling and advertising of
81 prescription drugs and biologics (21 U.S.C. 352 (a) & (n)).

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82

83 Section 201(m) of the FD&C Act defines *labeling* as “all labels and other written, printed, or graphic
84 matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article” (21
85 U.S.C. 321(m)).⁴ The U.S. Supreme Court has explained that the language “accompanying such article”
86 in the “labeling” definition is interpreted broadly, to include materials that supplement or explain an
87 article. No physical attachment between the materials and the article is necessary; rather, it is the textual
88 relationship between the items that is significant. *Kordel v. United States*, 335 U.S. 345, 350 (1948).
89 FDA generally recognizes two types of labeling for drugs: FDA-required labeling and promotional
90 labeling. Promotional labeling is generally any labeling, other than the FDA-required labeling, that is
91 devised for promotion of the product. Examples of promotional labeling pieces are described at 21 CFR
92 202.1(l)(2).

93

94 Also, under the FD&C Act and FDA's implementing regulations, the applicant shall submit specimens of
95 mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time
96 of initial dissemination of the labeling and at the time of initial publication of the advertisement for a
97 prescription drug product. Each submission is required to be accompanied by a completed Form FDA
98 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) (21 CFR
99 314.81(b)(3)(i) and 21 CFR 601.12(f)(4)).

100

101 For prescription and over-the-counter new animal drugs, the applicant must submit at the time of initial
102 dissemination one set of specimens of mailing pieces and other labeling. For prescription new animal
103 drugs, the applicant must also submit one set of specimens of any advertisement at the time of initial
104 publication or broadcast. Each submission of promotional labeling or advertisements must be
105 accompanied by a completed Form FDA 2301 (21 CFR 514.80(b)(5)(ii)).

106

107 IV. FACTORS CONSIDERED IN DETERMINING POSTMARKETING SUBMISSION 108 REQUIREMENTS FOR INTERACTIVE PROMOTIONAL MEDIA

109

110 FDA considers the following in determining a firm's responsibility for submitting interactive promotional
111 media to FDA as required by postmarketing submission requirements:

112

- 113 1. A firm is responsible for product promotional communications on sites that are owned, controlled,
114 created, influenced, or operated by, or on behalf of, the firm.

115

116 Such product promotional communications may include firm-sponsored microblogs (e.g., Twitter), social
117 networking sites (e.g., Facebook), firm blogs, and other sites that are under the control or influence of the
118 firm. In determining whether a firm must submit promotional material about its product(s) to FDA, the
119 Agency considers whether the firm, or anyone acting on its behalf, is influencing or controlling the
120 promotional activity or communication in whole or part. Thus, a firm is responsible if it exerts influence
121 over a site in any particular, even if the influence is limited in scope. For example, if the firm
122 collaborates on or has editorial, preview, or review privilege over the content provided, then it is
123 responsible for that content.

124

125 *Example 1:* A firm provides on its product website an online forum that gives users the opportunity to
126 post comments about the use of its product. In this case, the firm is responsible for submitting to FDA the
127 product website to meet the postmarketing submission requirements because the firm created, owns, or

⁴ See also 21 CFR 1.3(a).

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128 operates the website. (See the discussion regarding user generated content (UGC) on firm-owned or firm-
129 controlled venues at the end of this section.)

130

131 2. Under certain circumstances, a firm is responsible for promotion on third-party sites.

132

133 A firm is responsible for promotion on a third-party site if the firm has any control or influence on the
134 third-party site, even if that influence is limited in scope. For example, if a firm collaborates, or has
135 editorial, preview, or review privilege, then it is responsible for its promotion on the site and, as such, that
136 site is subject to submission to FDA to meet postmarketing submission requirements. However, if a firm
137 provides only financial support (e.g., through an unrestricted educational grant) and has no other control
138 or influence on that site, then the firm is *not* responsible for information on a third-party site, and has no
139 obligation to submit the content to FDA. Furthermore, if a firm is merely providing promotional
140 materials to a third-party site but does not direct the placement of the promotion within the site and has no
141 other control or influence on that site, the firm is responsible only for the content it places there and, thus,
142 is responsible only for submitting to FDA promotional content that was disseminated on that site.

143

144 *Example 2:* A firm does not have any control of, or influence on, information on an independent third-
145 party site but chooses to promote its product on this site (e.g., by providing specific promotional content
146 such as firm-initiated UGC). In this situation, to meet postmarketing submission requirements, the firm is
147 responsible for submitting to FDA the promotional content it provided to the site. (See Section V for
148 FDA's recommendations for how to submit.)

149

150 *Example 3:* A firm makes suggestions on the placement of its promotional messages on an independent
151 third-party site. Because the firm influenced the placement of its promotion within the third-party site,
152 the firm is responsible for submitting to FDA the promotion, along with the surrounding pages, to
153 adequately provide context to facilitate the review of the third-party site, in order to fulfill the
154 postmarketing submission requirements.

155

156 In summary, regardless of financial support, if a firm has any control of, or influence on, the third-party
157 site, even if limited in scope, it is responsible for submission to FDA to meet the postmarketing
158 submission requirements.

159

160 3. A firm is responsible for the content generated by an employee or agent who is acting on behalf of
161 the firm to promote the firm's product.

162

163 FDA's regulation of prescription drug product promotion extends both to promotional activities that are
164 carried out by the firm itself, and to promotion conducted on the firm's behalf. Therefore, a firm is
165 responsible for the content generated by its employees or any agents acting on behalf of the firm who
166 promote the firm's product. For example, if an employee or agent of a firm, such as a medical science
167 liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third-party
168 site about the firm's product, the firm is responsible for the content its employee or agent provides. A
169 firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.
170 Therefore, a firm is responsible for UGC and communications of its employees or anyone acting on
171 behalf of the firm and, as such, those materials are subject to submission to FDA to meet the
172 postmarketing submission requirements.

173

174 All UGC meeting these parameters for interactive promotional media should be submitted to the FDA as
175 recommended below in Section V.

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177 *Example 4:* A sales representative acting on behalf of a firm posts comments about the innovative release
178 mechanism of the firm’s product on an independent third-party site. Because the sales representative is
179 acting on behalf of the firm, the firm is responsible for submitting the comments to FDA to meet the
180 postmarketing submission requirements.

181
182 *Example 5:* A representative of a firm, such as a blogger paid by the firm, maintains a blog about the
183 firm’s product. The firm is responsible for submitting the blog to FDA to meet the postmarketing
184 submission requirements.

185
186 FDA recommends that a firm be transparent in disclosing its involvement on a site by clearly identifying
187 the UGC and communications of its employees or third parties acting on behalf of the firm. This could be
188 achieved by inclusion of the firm's identifier (e.g., name or logo) as part of the communication. However,
189 a firm generally is not responsible for UGC that is truly independent of the firm (i.e., is not produced by,
190 or on behalf of, or prompted by the firm in any particular).⁵ FDA will not ordinarily view UGC on firm-
191 owned or firm-controlled venues such as blogs, message boards, and chat rooms as promotional content
192 on behalf of the firm as long as the user has no affiliation with the firm and the firm had no influence on
193 the UGC.

194
195 FDA recommends that a firm submit to the Agency on Form FDA 2253 or Form FDA 2301 specimens of
196 the interactive promotional media being used on the firm-owned or firm-controlled venue (e.g., blog,
197 message board, or chat room), as described below in Section V. FDA recognizes that firms may be
198 submitting both firm-generated and independent UGC on Form FDA 2253 or Form FDA 2301 as both
199 firm-generated and independent UGC may be dispersed throughout the interactive promotional venue.

200 201 **V. RECOMMENDATIONS FOR SUBMITTING INTERACTIVE PROMOTIONAL MEDIA**

202
203 FDA recognizes the challenges of submitting promotional materials that display real-time information
204 and, in this section, recommendations for submitting interactive promotional media are provided. If a
205 firm submits interactive promotional media in the manner described in this draft guidance, FDA intends
206 to exercise enforcement discretion regarding the regulatory requirements for postmarketing submissions
207 related to promotional labeling and advertising. However, the Agency’s expectations for submitting static
208 promotional materials (e.g., sites that do not allow real-time communications and emails with
209 predetermined content) that are substantially similar to traditional promotional materials in presentation
210 and content remain unchanged.⁶

211
212 Unless otherwise specified in this guidance, the principles set forth below apply to the submission of
213 interactive promotional media that display real-time communications, regardless of the target audience.

⁵ Cf. 47 U.S.C. 230(c)(1) (“no provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider”). The Communications Decency Act further defines “information content provider” as someone “responsible, in whole or in part, for the creation or development of information provided through the Internet or any other interactive computer service.” 47 U.S.C. 230(f)(3).

⁶ Please note that the Agency expects that submissions of static promotional materials should remain unchanged. For example, a firm should submit its entire static product website at the time of first use. If the firm then updates one page or section of this static product website, the firm can submit only the updated page or section with a cross-reference to the original submission of the website noted on Form FDA 2253 or Form FDA 2301, including the date of the original submission. If the website is substantially revised, the firm should submit the revised website in its entirety.

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214 The examples and recommendations provided are intended to provide guidance and illustrate possible
215 approaches. Firms are free to use alternative approaches if these approaches satisfy the requirements of
216 the statute and regulations.

217
218 1. At the time of initial display, a firm should submit in its entirety all sites for which it is responsible
219 on Form FDA 2253 or Form FDA 2301. For example, the firm should submit the comprehensive
220 static product website with the addition of the interactive or real-time components.⁷

221
222 The firm should include annotations to describe the parts that are interactive and allow for real-time
223 communications. Any subsequent changes should be annotated and resubmitted to the Agency on Form
224 FDA 2253 or Form FDA 2301 at the time of initial display (i.e., resubmission). The firm should also
225 provide a cross-reference by noting the submission date of the most recent version of the site in the
226 comments section of the form. However, after the initial submission or resubmission, if the site is
227 publically accessible without restrictions such as a password or subscription (“non-restricted”) and
228 remains unchanged other than displaying real-time information, FDA does not intend to object if the firm
229 submits to the Agency on Form FDA 2253 or Form FDA 2301 an updated listing of the site that does not
230 include screenshots or other visual representations of the actual interactive or real-time communication, as
231 described in number 3 below. If access to the site is restricted (e.g., is password protected or a
232 subscription is required), see number 4 below.

233
234 2. For third-party sites on which a firm’s participation is limited to interactive or real-time
235 communications, a firm should submit the home page of the third-party site, along with the
236 interactive page within the third-party site and the firm’s first communication, on Form FDA 2253 or
237 Form FDA 2301 at the time of initial display.

238
239 The firm may include any annotations that describe its communications within the third-party site. After
240 the initial submission, if the firm remains an active participant on the third-party site, and that site is non-
241 restricted, FDA does not intend to object if the firm submits to the Agency on Form FDA 2253 or Form
242 FDA 2301 an updated listing of the site that does not include screenshots or other visual representations
243 of the actual interactive or real-time communication, as described in number 3 below. If access to the site
244 is restricted, see number 4 below.

245
246 3. Once every month, a firm should submit an updated listing of all non-restricted sites for which it is
247 responsible or in which it remains an active participant and that include interactive or real-time
248 communications. Firms need not submit screenshots or other visual representations of the actual
249 interactive or real-time communications with the monthly updates.

250
251 Once every month, the firm should submit a Form FDA 2253 or Form FDA 2301 for the non-restricted
252 sites for which the firm is responsible or in which it remains an active participant and that include
253 interactive or real-time communications. Multiple sites and the corresponding documents can be
254 submitted with a single Form FDA 2253 or Form FDA 2301. Firms should include a separate document
255 for each site which includes the site name, URL, and date range, as well as a cross-reference to the date of
256 the most recent submission of the site. Screenshots or other visual representations of the actual
257 interactive or real-time communications need not be submitted with the monthly updates if the site is non-

⁷ It is preferable for the firm to submit the interactive or real-time communications in an archivable format that allows FDA to view and interact with the submission in the same way as the end user (e.g., working links). Alternatively, firms should submit screen shots or other visual representations.

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258 restricted. The appropriate FDA center (CDER, CBER, or CVM) should be informed via general
259 correspondence on the first day the firm ceases to be active on a site.

260

261 4. However, if a site has restricted access and, as such, FDA may not have access to the site, a firm
262 should submit all content related to the discussion (e.g., all UGC about the topic), which may or may
263 not include independent UGC, to adequately provide context to facilitate the review. Screenshots or
264 other visual representations of the actual site, including the interactive or real-time communications,
265 should be submitted monthly on Form FDA 2253 or Form FDA 2301.

266

267 5. When submitting the site, FDA recommends that a firm take formatting factors (e.g., appearance,
268 layout, visual impression) into consideration to enable the Agency to view the communications as a
269 whole.