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# **Guidance for Industry Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices**

## ***DRAFT GUIDANCE***

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For questions regarding this draft document, contact (CDER) Jean-Ah Kang at 301-796-1200; (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800; (CVM) Dorothy McAdams at 240-453-6802; or (CDRH) Deborah Wolf at 301-796-5732.

**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)  
Center for Devices and Radiological Health (CDRH)**

**June 2014  
Advertising**

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# Guidance for Industry Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

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10903 New Hampshire Ave., Bldg. 51, rm. 2201  
Silver Spring, MD 20993-0002  
Tel: 301-796-3400; Fax: 301-847-8714;  
E-mail: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)*

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Center for Biologics Evaluation and Research  
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10903 New Hampshire Ave., WO71, Room 3128  
Silver Spring, MD 20993  
Tel: 800-835-4709 or 240-402-7800;  
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*Communications Staff (CVM)  
Center for Veterinary Medicine  
Food and Drug Administration  
7519 Standish Place, HFV-12  
Rockville, MD 20855  
Tel: 240-276-9300;  
E-mail: [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov)*

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Center for Devices and Radiological Health  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 66, rm. 5431  
Silver Spring, MD 20993-0002  
Tel: 301-796-5900;*

*E-mail: [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov)  
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## **Guidance for Industry<sup>1</sup>**

### **Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices**

This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s or Agency’s) current thinking on this topic.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, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title pages of this guidance.

#### **I. INTRODUCTION**

This draft guidance is intended to describe FDA’s current thinking about how manufacturers, packers, and distributors (firms) of prescription human and animal drugs (drugs) and medical devices for human use (devices)<sup>2</sup> that choose to present benefit information should present both benefit and risk information within advertising and promotional labeling (sometimes collectively referred to in this guidance document as “promotion”) of their FDA-regulated medical products on electronic/digital platforms that are associated with character space limitations—specifically on the Internet and through social media or other technological venues (Internet/social media). Examples of Internet/social media platforms with character space limitations include online microblog messaging (e.g., messages on Twitter or “tweets,” which are currently limited to 140 character spaces per tweet) and online paid search (e.g., “sponsored links” on search engines such as Google and Yahoo, which have limited character spaces as well as other platform-imposed

<sup>1</sup> 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), the Center for Veterinary Medicine (CVM), and the Center for Devices and Radiological Health (CDRH).

<sup>2</sup> 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 regulation under 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)). References to “drugs” and “devices” in this guidance therefore also include biological products that fall within each of those definitions. 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. This draft guidance does not address devices solely intended for use in animals.

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30 considerations).<sup>3</sup> This draft guidance presents considerations to illustrate FDA’s thinking on  
31 factors that are relevant to the communication of benefit and risk information on Internet/social  
32 media platforms with character space limitations.<sup>4</sup>  
33

34 Please note that this draft guidance does not address promotion via product websites, webpages on  
35 social media networking platforms (e.g., individual product pages on websites such as Facebook,  
36 Twitter, YouTube), and online web banners, as the Agency believes that these specific types of  
37 Internet/social media platforms do not impose the same character space constraints as online  
38 microblog messaging and online paid search. This draft guidance also does not address responsive  
39 web design or other technology-specific layout features that may result in product promotion  
40 presentations that differ depending on the technology used to view them (e.g., desktop computer  
41 monitors, mobile devices, tablets).  
42

43 FDA’s guidance documents, including this draft guidance, do not establish legally enforceable  
44 rights or responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and  
45 should be viewed only as recommendations, unless specific regulatory or statutory requirements  
46 are cited. The use of the word *should* in Agency guidances means that something is suggested or  
47 recommended, but not required.  
48

49 **II. BACKGROUND**

50  
51 Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Agency has responsibility for  
52 regulating the manufacture, sale, and distribution of drugs and medical devices in the United  
53 States. This authority includes oversight of the labeling of drugs and medical devices (21 U.S.C.  
54 352(a)) and the advertising of prescription drugs and restricted medical devices (21 U.S.C. 352(n),  
55 (q), and (r)).<sup>5</sup>  
56

57 Section 201(m) of the FD&C Act defines *labeling* as “all labels and other written, printed, or  
58 graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such  
59 article” (21 U.S.C. 321(m)).<sup>6</sup> The U.S. Supreme Court has explained that the language  
60 “accompanying such article” in the “labeling” definition is interpreted broadly, to include materials  
61 that supplement or explain an article. No physical attachment between the materials and the article  
62 is necessary; rather, it is the textual relationship between the items that is significant (*Kordel v.*

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<sup>3</sup> While online microblog messaging and online paid search examples are specifically illustrated within this draft guidance, FDA’s recommendations may also apply to advertising and promotional labeling on other types of Internet/social media platforms with character space limitations.

<sup>4</sup> This guidance document focuses on use of character-space-limited platforms by firms to make claims about their legally marketed drugs and devices that are consistent with their approved or required labeling. Representations by a firm in character-space-limited platforms may also provide evidence of the intended use of the product, but that issue is not the focus of this draft guidance.

<sup>5</sup> Devices may become restricted by regulation issued under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)), by performance standard issued pursuant to section 514(a)(2)(B)(v) (21 U.S.C. 360d(a)(2)(B)(v)), or by order approving an application for premarket approval (i.e., a PMA) pursuant to section 515(d)(1)(B)(ii) (21 U.S.C. 360e(d)(1)(B)(ii)).

<sup>6</sup> See also 21 CFR 1.3(a).

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63 *United States*, 335 U.S. 345, 350 (1948)). FDA generally recognizes two types of labeling: (1)  
64 FDA-required labeling<sup>7</sup> and (2) promotional labeling. Promotional labeling is generally any  
65 labeling, other than the FDA-required labeling, that is devised for promotion of the product.  
66 Examples of materials that may be considered promotional labeling pieces for prescription drugs  
67 are described in 21 CFR 202.1(l)(2). The scope of labeling for prescription medical devices is  
68 described in 21 CFR 801.109.

69  
70 The FD&C Act does not define what constitutes an “advertisement,” but FDA regulations provide  
71 several examples, including “advertisements in published journals, magazines, other periodicals,  
72 and newspapers, and advertisements broadcast through media such as radio, television, and  
73 telephone communication systems” (21 CFR 202.1(l)(1)).

74  
75 Under the FD&C Act and FDA's implementing regulations, promotional labeling for drugs and  
76 devices and advertisements for prescription drugs and restricted devices misbrand the product if  
77 they make representations about the use of a firm's product without disclosing certain information  
78 about the product's risk (FD&C Act sections 502(a)(n)(q)(r), 201(n); 21 CFR 1.21(a); 21 CFR  
79 201.1). When using Internet/social media platforms with character space limitations for product  
80 promotion, firms should consider the following provisions<sup>8</sup>:

- 81
- 82 • Any promotional labeling for a drug or device must be truthful and non-misleading (FD&C  
83 Act sections 502(a), 201(n)).
  - 84
  - 85 • Any promotional labeling that makes claims about a firm's prescription drug or prescription  
86 device must include certain information, such as the indicated use of the product and the risks  
87 associated with use of the product (21 CFR 201.100(d), 201.105(d) and 801.109(d)).
  - 88
  - 89 • Pursuant to section 502(c) for drugs and devices, information required to appear on the label or  
90 labeling must be placed prominently thereon with such conspicuousness and in such terms as  
91 to render it likely to be read and understood by the ordinary individual under customary  
92 conditions of purchase and use.
  - 93

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<sup>7</sup> Much FDA-required labeling is subject to FDA review and approval. For example, after drafting by the manufacturer, labeling is reviewed and approved by FDA as part of the new drug application (NDA), new animal drug application (NADA), biologics license application (BLA) or premarket approval application (PMA) review (see 21 CFR 314.50(c)(2), 514.1(b)(3), 601.2(a), 814.20(b)(10) and 814.44(d)). For devices that are subject to premarket notification (510(k)) requirements, the 510(k) must contain the proposed labeling sufficient to describe the device, its intended use, and the directions for its use (21 CFR 807.87(e)). All devices, including those exempt from premarket review, are subject to the requirements of applicable labeling regulations, including requirements for adequate directions for use (see 21 CFR Part 801). For a prescription drug or prescription device to be exempted from the FD&C Act's requirement of adequate directions for use (21 U.S.C. 352(f)(1)), its FDA-required labeling must contain, among other information, information addressing product hazards and other risk information, as specified in FDA regulations (21 CFR 201.100(d)(1), (3), 201.105(c)(1), and 801.109).

<sup>8</sup> This is not an exhaustive list.

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- 94 • Any advertising that makes representations about the use of a firm’s prescription drug must  
95 include certain risk information (FD&C Act section 502(n); 21 CFR 202.1).<sup>9</sup> Similarly,  
96 section 502(r) of the FD&C Act requires a “brief statement of intended uses” and relevant risk  
97 information in restricted-device advertising. Section 502(q) of the FD&C Act provides that  
98 restricted-device advertising that “is false or misleading in any particular” misbrands the  
99 device. Note that “reminder” promotion, which calls attention to the name of a product but  
100 does not make any representations or suggestions about the product, is exempt from many of  
101 these labeling and advertising disclosure requirements (21 CFR 200.200, 201.100(f),  
102 201.105(d)(2), 202.1(e)(2)(i), 801.109(d)).<sup>10</sup>  
103
- 104 • Prescription drug advertisements must present a fair balance between information relating to  
105 risk and information relating to benefit (21 CFR 202.1(e)(5)(ii)). In addition, risk information  
106 must be presented with a prominence and readability reasonably comparable to claims about  
107 drug benefits (21 CFR 202.1(e)(7)(viii)).  
108
- 109 • Furthermore, for prescription drug advertisements to be truthful and non-misleading, they must  
110 contain risk information in each part, as necessary, to qualify any representations and/or  
111 suggestions made in that part about the drug. The risk information may be concise if  
112 supplemented by a prominent reference to the presence and location elsewhere in the  
113 advertisement of a more complete discussion (21 CFR 202.1(e)(3)(i)).  
114
- 115 • In addition, section 201(n) of the FD&C Act provides that in determining whether a drug or  
116 device is misbranded because its labeling or advertising is misleading, it must be considered  
117 whether the labeling or advertising fails to reveal facts that are material with respect to possible  
118 consequences of the use of the product as represented in the labeling or advertising or under  
119 conditions of use that are customary or usual.  
120

121 Risk information should be comparable in content and prominence to benefit claims within the  
122 product promotion (i.e., a balanced presentation). Achieving a balanced presentation requires  
123 firms to carefully consider the desired benefit claims and risk profiles for their products when  
124 choosing a promotional platform. FDA acknowledges that Internet/social media platforms  
125 associated with character space limitations may pose challenges for firms in providing a balanced  
126 presentation of both risks and benefits of medical products, as discussed above.  
127

---

<sup>9</sup> As set forth above, with regard to devices, the Agency’s authority over promotional labeling extends to all devices, whereas its authority over advertising extends to restricted devices. Regardless of the type of device, FDA encourages firms to use the practices outlined in this guidance to benefit the public health.

<sup>10</sup> This draft guidance does not apply to those *reminder* promotions (labeling or advertising that calls attention to the name of a drug or device but does not include indications, dosage recommendations, or other information) that are exempted by regulation from the requirements under the FD&C Act for the disclosure of risk information. See 21 CFR 200.200, 201.100(f), 201.105(d)(2), 202.1(e)(2)(i), 801.109(d). But see 21 U.S.C. 352(r) (requiring certain risk information in all restricted-device advertisements).

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128 FDA is issuing this draft guidance to aid firms in effectively communicating benefit and risk  
129 information in product promotion using character-space-limited platforms such as online  
130 microblog messaging and online paid search.<sup>11</sup> However, regardless of the platform, truthful,  
131 accurate, non-misleading, and balanced product promotion best serves the public health. For some  
132 products, particularly those with complex indications or extensive serious risks, character space  
133 limitations imposed by platform providers may not enable meaningful presentations of both benefit  
134 and risk (although they may be sufficient for “reminder” promotions—see footnote 10). If an  
135 accurate and balanced presentation of both risks and benefits of a specific product is not possible  
136 within the constraints of the platform, then the firm should reconsider using that platform for the  
137 intended promotional message (other than for permitted reminder promotion).  
138

139 **III. OVERVIEW OF FDA’S POLICY ON PRESENTING RISK AND BENEFIT**  
140 **INFORMATION ON INTERNET/SOCIAL MEDIA PLATFORMS WITH**  
141 **CHARACTER SPACE LIMITATIONS**  
142

143 Regardless of character space constraints that may be present on certain Internet/social media  
144 platforms, if a firm chooses to make a product benefit claim, the firm should also incorporate risk  
145 information within the same character-space-limited communication. The firm should also  
146 provide a mechanism to allow direct access to a more complete discussion of the risks associated  
147 with its product.  
148

149 Section IV discusses general factors that firms should consider in the communication of benefit  
150 information on Internet/social media platforms with character space limitations, which directly  
151 impacts the communication of risk information. Section V explains in detail the factors that FDA  
152 considers in the disclosure of risk information on Internet/social media platforms with character  
153 space limitations. Section VI provides firms with additional recommendations for the inclusion of  
154 other product information (including certain required product information other than risk/benefit  
155 information, as applicable) on Internet/social media platforms with character space limitations.  
156

157 Please note that sections IV, V, and VI provide hypothetical examples<sup>12</sup> that, when taken in  
158 totality, illustrate FDA’s recommendations for how firms may disseminate product promotion on  
159 Internet/social media platforms with character space limitations. The examples build on the  
160 considerations set forth from the previous section and are numbered accordingly to identify related  
161 examples (e.g., examples 1A, 1B, and 1C are related to the same hypothetical product—example  
162 1A incorporates benefit information, example 1B adds risk information to example 1A, and  
163 example 1C provides additional recommendations for examples 1A and 1B to illustrate, in totality,

---

<sup>11</sup> CDER’s OPDP, formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC), issued 14 enforcement letters involving sponsored link promotion on Apr 2, 2009 (see FDA’s enforcement website available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm055773.htm>).

<sup>12</sup> The hypothetical examples involve fictitious products and are not an endorsement of the fictitious product names.



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164 a final example of promotion on an Internet/social media platform with character space limitations  
165 to which the Agency would not intend to object).

166  
167 FDA recommends that firms first carefully consider the complexity of the indication and risk  
168 profiles for each of their products to determine whether a character-space-limited platform is a  
169 viable promotional tool for a particular product, and then take the factors, recommendations, and  
170 hypothetical examples outlined in this guidance document into account when developing benefit  
171 and risk presentations. The public health is best served when risk and effectiveness information  
172 about drug and device products is clearly and accurately communicated.

173  
174 **IV. GENERAL FACTORS CONSIDERED IN THE COMMUNICATION OF BENEFIT**  
175 **INFORMATION ON INTERNET/SOCIAL MEDIA PLATFORMS WITH**  
176 **CHARACTER SPACE LIMITATIONS**

177  
178 When the Agency evaluates advertising and promotional labeling for compliance with the FD&C  
179 Act and FDA’s implementing regulations, it determines whether claims about both the benefits and  
180 risks of the product are accurate and non-misleading. The Agency also looks at whether benefits  
181 and risks are presented in a comparably prominent manner (as outlined above in section II). Thus,  
182 considerations involving the content and format of benefit information are an inherent part of  
183 FDA’s evaluation of risk presentations on Internet/social media platforms.

184  
185 In communicating benefit information on Internet/social media platforms with character space  
186 limitations, firms should consider the following points:

- 187  
188 1. Benefit information should be accurate and non-misleading and reveal material facts within  
189 each individual character-space-limited communication (e.g., each individual message or  
190 tweet).

191  
192 When communicating benefit information about its product, a firm should ensure that benefit  
193 information is accurate and non-misleading. In doing so, the firm should also reveal material facts  
194 about the use of its product, such as limitations to an indication or the relevant patient population.  
195 For example, a firm should refer to the “Indications and Usage” portion of the Highlights of  
196 Prescribing Information that is available for many human prescription drugs to help determine  
197 what information to convey, although the firm is generally not required to use the precise wording  
198 found there. Labeling for an approved premarket approval application (PMA) for class III medical  
199 devices or use information consistent with a cleared intended use for 510(k) medical devices  
200 provides the basis for the benefit information related to devices. Such information would include  
201 material facts that the firm should present within the individual character-space-limited  
202 communication because, without doing so, the benefit information in totality may be misleading.

- 203  
204 2. Benefit information should be accompanied by risk information within each individual  
205 character-space-limited communication.

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207 A firm should also consider whether, once benefit information is conveyed in an accurate and non-  
208 misleading manner, enough capacity will remain in the character-space-limited communication to  
209 adequately convey required risk information. Please refer to section V for factors firms should  
210 consider in the disclosure of risk information. In addition, a firm should consider whether enough  
211 capacity will remain in the character-space-limited communication to adequately convey certain  
212 other required information, as applicable. Please refer to section VI for additional  
213 recommendations firms should consider for the inclusion of other product information.

214

215 3. If a firm concludes that adequate benefit and risk information, as well as other required  
216 information, cannot all be communicated within the same character-space-limited  
217 communication, then the firm should reconsider using that platform for the intended  
218 promotional message.

219

220 **Example 1A:** A firm is considering promotion of its prescription drug *NoFocus* on Twitter, which  
221 is limited to 140 character spaces per message or tweet. *NoFocus* is indicated for mild to moderate  
222 memory loss. Any benefit information that the firm communicates about *NoFocus* should be  
223 accurate and non-misleading and include material facts about the use of *NoFocus*, i.e., that it is  
224 indicated for **mild to moderate** memory loss.

225

226 The firm considers including the following benefit information within the tweet [the information in  
227 brackets denotes character spaces used/140 available character spaces in a tweet]:

228

229 NoFocus for mild to moderate memory loss [40/140]

230

231 The benefit information for *NoFocus* that is communicated within the first 40 character spaces of  
232 this tweet is accurate and non-misleading and includes material facts about the indication and  
233 limitations to the use of *NoFocus*. The firm should consider whether the remaining 100 character  
234 spaces are enough to include risk information and certain other required information, as applicable,  
235 about *NoFocus*. See examples 1B and 1C in sections V and VI in this draft guidance, respectively,  
236 for further considerations on the disclosure of risk and other information for *NoFocus* within this  
237 tweet. If the firm concludes that adequate benefit and risk information, as well as other required  
238 information, cannot all be communicated within the same tweet, then the firm should reconsider  
239 using Twitter for the intended promotional message for *NoFocus*.

240

241 **Example 2A:** A firm is considering promotion of its prescription drug *Headhertz* using Google's  
242 Sitelink extensions (sponsored link promotion that contains character space limitations and specific  
243 formatting requirements, sometimes referred to in this guidance document as "Sitelinks").<sup>13</sup>

244 *Headhertz* is indicated for severe headache associated with traumatic brain injury. Any benefit  
245 information that the firm communicates about *Headhertz* should be accurate and non-misleading

---

<sup>13</sup> The example featured in this guidance relies on one specific Google formatting option (current as of Jan 22, 2014); however, it may be possible to follow the concepts outlined in this draft guidance for other types of sponsored link promotion or Internet/social media platforms with character space limitations.

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246 and include material facts about the use of *Headhertz*, i.e., that it is indicated for **severe** headache  
247 **associated with traumatic brain injury**.

248  
249 The firm considers including the following benefit information within the sponsored link  
250 promotion [the information in brackets denotes character spaces used/available character spaces  
251 per line of the sponsored link promotion]:

252  
253           Headhertz [9/25]  
254           [www.headhertz.com](http://www.headhertz.com) [17/35]  
255           For severe headache from traumatic brain injury [47/70]

256  
257 The benefit information for *Headhertz* that is communicated within the character spaces for this  
258 specific sponsored link format is accurate and non-misleading and includes material facts about the  
259 indication and limitations to the use of, and the specific patient population for, *Headhertz*. The  
260 firm should consider whether risk information and certain other required information, as  
261 applicable, about *Headhertz* can also be included within the remaining character spaces for this  
262 specific sponsored link format. See examples 2B and 2C in sections V and VI in this draft  
263 guidance, respectively, for further considerations on the disclosure of risk and other information  
264 for *Headhertz* within this sponsored link format. If the firm concludes that adequate benefit and  
265 risk information, as well as other required information, cannot all be communicated within this  
266 same sponsored link format, then the firm should reconsider using Google’s Sitelinks for the  
267 intended promotional message for *Headhertz*.

268  
269 **V. FACTORS CONSIDERED IN THE DISCLOSURE OF RISK INFORMATION ON**  
270 **INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE**  
271 **LIMITATIONS**

272  
273 This section of the draft guidance outlines factors considered in the disclosure of risk information  
274 on Internet/social media platforms with character space limitations. As previously stated,  
275 regardless of character space constraints that may be present on certain Internet/social media  
276 platforms, if a firm chooses to make a product benefit claim, the firm should also incorporate risk  
277 information within the same character-space-limited communication. The firm should also  
278 provide a mechanism to allow direct access to a more complete discussion of the risks associated  
279 with its product.

280  
281 In general, the Agency considers two primary factors to determine whether risk information is  
282 comparable in scope to benefit information within promotional materials: (1) whether the risk  
283 information qualifies any representations made about the product (i.e., content of the risk  
284 information compared to content of the benefit information) and (2) whether the risk information is  
285 presented with a prominence and readability comparable to the benefit claims about the product.<sup>14</sup>

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<sup>14</sup> FDA has developed separate draft guidance that, when final, will represent the Agency’s current thinking on how firms should, in general, present risk information in other types of promotional materials. See the draft guidance for

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286  
287 However, the Agency is aware of the challenges in balancing benefit and risk information within  
288 the character space constraints of certain Internet/social media platforms—particularly in terms of  
289 content—because of the sheer volume of information. The Agency believes that a concise  
290 disclosure of specific risk information may be presented together with benefit information within  
291 the confines of character-space-limited Internet/social media platforms if supplemented by a  
292 prominent reference to the presence and location elsewhere of a more complete discussion of the  
293 risks associated with the product (or for restricted-device advertising, a “brief statement” of  
294 intended use and relevant risk information) and that this is consistent with requirements of the  
295 FD&C Act and FDA’s implementing regulations (see section II). These concepts are further  
296 elucidated below in this section of the guidance document.

297  
298 In communicating risk information on Internet/social media platforms with character space  
299 limitations, firms should consider the following points:

- 300  
301 1. Risk information should be presented together with benefit information within each individual  
302 character-space-limited communication (e.g., each individual message or tweet).  
303  
304 2. The content of risk information presented within each individual character-space-limited  
305 communication should, at a minimum, include the most serious risks associated with the  
306 product.

307  
308 At a minimum, a firm should communicate the most serious risks associated with the product  
309 together with the benefit information within the individual character-space-limited communication.  
310 For a prescription human drug, the most serious risks would generally include all risk concepts  
311 from a boxed warning, all risks that are known to be fatal or life-threatening, and all  
312 contraindications<sup>15</sup> from the approved product labeling (the PI). If a prescription human drug does  
313 not have a boxed warning, fatal or life-threatening risks, or any contraindications, the most  
314 significant warnings or precautions about the product should be communicated. For animal drugs,  
315 the most serious risks would include potential injury to human handlers/animal patients and risk of  
316 drug residues entering the human food chain. For devices, if a particular risk is associated with a  
317 particular identifiable use or population, then each of those should be included. The Agency  
318 believes that communication of the most serious risks as outlined above would provide a concise  
319 statement of risk information about the product for promotion on Internet/social media platforms  
320 with character space limitations.

321

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industry entitled *Presenting Risk Information in Prescription Drug and Medical Device Promotion* available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf>.

<sup>15</sup> For prescription human drugs, if the only contraindication listed in the PI is hypersensitivity, the Agency would not expect that contraindication to be included as part of the risk disclosure within the character-space-limited communication unless there were documented cases of hypersensitivity occurring in patients who took the product.

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322 3. A mechanism, such as a hyperlink, should also be provided within each individual character-  
323 space-limited communication to allow direct access to a more complete discussion of risk  
324 information about the product.

325  
326 In addition to presenting the most serious risks within the individual character-space limited  
327 communication, FDA recommends that a firm also include in that communication a *direct*  
328 hyperlink to a destination (e.g., landing page) that is devoted exclusively to the communication of  
329 risk information about the product. Examples of such landing pages providing direct and exclusive  
330 access to risk information could include a website devoted to providing comprehensive risk  
331 information about the product, a particular webpage within a website that is devoted to providing  
332 comprehensive risk information about the product, or a portable document format (PDF) file that is  
333 devoted to providing comprehensive risk information about the product. An example that the  
334 Agency would not consider to provide direct and exclusive access to risk information would  
335 include a hyperlink only to a product’s home page that also includes benefit information and other  
336 claims or graphics. Firms may include *supplemental* hyperlinks (e.g., to a product home page, to a  
337 PI, or to a brief summary) either within the character-space-limited communication itself or on the  
338 landing page of risk information, but the Agency recommends that a direct hyperlink to a landing  
339 page that is devoted exclusively to comprehensive risk information about the product be initially  
340 included within the original character-space-limited communication.<sup>16</sup>

341  
342 Many Internet/social media platforms allow the use of uniform resource locator (URL) shortening  
343 services, which are likely to result in a URL or web address with fewer character spaces. The  
344 Agency does not intend to object to the use of such URL shortening services; however, when  
345 possible, the Agency recommends that the URL or web address itself denote to the user that the  
346 landing page consists of risk information (e.g., [www.product.com/risk](http://www.product.com/risk)). Please note that if the  
347 URL or web address itself is promotional in content or tone, FDA may take into consideration  
348 whether any resulting claims are false or misleading or provide evidence in support of other  
349 violations under the FD&C Act and FDA’s implementing regulations (e.g., a URL such as  
350 [www.bestcancercuredrug.com](http://www.bestcancercuredrug.com) may be misleading).

351  
352 4. The prominence of risk information should be comparable to the benefit information within  
353 each individual character-space-limited communication, taking into consideration any  
354 formatting capabilities available on the specific Internet/social media platform.

355  
356 If a firm uses techniques to emphasize benefit information within the character-space-limited  
357 communication, the firm should consider similar techniques to achieve comparable emphasis of

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<sup>16</sup> A firm should consider how to fulfill other regulatory requirements for advertising or promotional labeling as applicable, such as providing an accompanying brief summary or PI with promotion for a drug (see 202.1(e)(1) and 201.100(d)). Where such requirements apply, the Agency expects that a firm would provide access to a brief summary or PI to accompany the communication in the character-space-limited Internet/social media platform, for example, by providing a direct hyperlink to those materials either within the character-space-limited communication itself or on the landing page of risk information. However, note that a link to a brief summary or PI should not be used **in place of** disclosing risk information within the original character-space-limited communication.

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358 risk information for its product.<sup>17</sup> Additionally, FDA recommends that, where the platform  
359 enables the use of different formatting, a firm utilize those formatting capabilities to highlight  
360 significant risk information, such as a boxed warning (e.g., a firm should present the boxed  
361 warning in bolded text to convey the seriousness of that particular risk for its product).  
362

363 **Example 1B** (continued from example 1A): A firm is considering promotion of its prescription  
364 drug *NoFocus* on Twitter, which is limited to 140 character spaces per message or tweet. *NoFocus*  
365 is indicated for mild to moderate memory loss. There are no boxed or other warnings and no  
366 known fatal or life-threatening risks included in the PI for *NoFocus*. The most serious precaution  
367 associated with *NoFocus* is that it may cause seizures in patients with a seizure disorder. Since  
368 benefit information was provided within the tweet (example 1A), the firm should communicate, at  
369 a minimum, the most serious risks associated with *NoFocus* within the same tweet. The firm  
370 should also include within the same tweet a direct hyperlink to a more complete discussion of risk  
371 information about *NoFocus*. Additionally, the prominence of risk information should be  
372 comparable to the benefit information contained within the tweet, taking into consideration any  
373 formatting capabilities that may be available.  
374

375 The firm considers including the following benefit and risk information within the tweet:  
376

377       NoFocus for mild to moderate memory loss; may cause seizures in patients with a seizure  
378       disorder [www.nofocus.com/risk](http://www.nofocus.com/risk) [117/140]  
379

380 In the above example, benefit information for *NoFocus* is accurate and non-misleading, and the  
381 most serious risks associated with *NoFocus* are communicated together with the benefit  
382 information within the tweet. The firm includes a direct hyperlink to the “Important Safety  
383 Information” webpage (within the product website) that is devoted to providing comprehensive  
384 risk information about *NoFocus*. In addition, the URL [www.nofocus.com/risk](http://www.nofocus.com/risk) (emphasis added)  
385 denotes that the landing page is comprised of risk information, and the URL is not promotional in  
386 tone. The firm conveys risk information within the tweet in a comparable manner to the benefit  
387 information. See example 1C in section VI in this draft guidance for further considerations on the  
388 inclusion of other product information for *NoFocus* within this tweet.  
389

390 **Example 2B** (continued from example 2A): A firm is considering promotion of its prescription  
391 drug *Headhurtz* using Google’s Sitelinks.<sup>18</sup> *Headhurtz* is indicated for severe headache associated

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<sup>17</sup> FDA acknowledges that providers of character-space-limited platforms frequently dictate aspects controlling the presentation of text that affect prominence and readability (e.g., font size and style). Where the platform provider only permits one type of text, issues affecting comparability are less likely to arise.

<sup>18</sup> Google’s “Sitelink extensions” format allows up to six additional links (Sitelinks) to be shown in addition to the display URL (www.headhurtz.com in this example). Under parameters set by Google, the link text for each of the Sitelinks must be 25 characters or fewer. The link text must directly relate to the content on the landing page for that link and point to different content, i.e., no Sitelinks may lead to the same landing page or to the same content. In addition, Sitelinks may not direct to the same landing page as the destination URL (the landing page for www.headhurtz.com in this example). Furthermore, up to two optional description lines (35 characters or fewer per line) may be created for display underneath each of the Sitelinks. This information is current as of Jan 22, 2014;

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392 with traumatic brain injury. The PI for *Headhertz* includes a boxed warning about the potential for  
393 brain swelling and warnings about a potentially fatal drug reaction and a drop in heart rate that  
394 may be life-threatening. Since benefit information was provided within the sponsored link format  
395 (example 2A), the firm should communicate, at a minimum, the most serious risks associated with  
396 *Headhertz* within the same sponsored link format. The firm should also include within the same  
397 sponsored link format a direct hyperlink to a more complete discussion of risk information about  
398 *Headhertz*. Additionally, the prominence of the risk information should be comparable to the  
399 benefit information contained within the sponsored link format, taking into consideration any  
400 formatting capabilities that may be available.

401  
402 The firm considers including the following benefit and risk information within the sponsored link  
403 promotion:

404  
405 Headhertz [9/25]  
406 www.headhertz.com [17/35]  
407 For severe headache from traumatic brain injury [47/70]  
408 Boxed warning [13/25] Warning [7/25]  
409 Potential for brain swelling [28/35] Potentially fatal drug reaction [31/35]  
410 Warning [7/25] Risk information [16/25]  
411 Life-threatening drop in heart rate [35/35] Important safety information [28/35]  
412

413 In the above example, benefit information for *Headhertz* is accurate and non-misleading.  
414 Consistent with the Google-imposed formatting requirements outlined in footnote 18, the firm  
415 chooses to utilize three of the six Sitelinks to convey the most serious risks associated with  
416 *Headhertz*, including the boxed warning and additional warnings about fatal and life-threatening  
417 risks. Therefore, the most serious risks associated with *Headhertz* are communicated together with  
418 the benefit information within the sponsored link format. The firm also includes a fourth Sitelink  
419 that provides direct access to a more complete discussion of risk information about *Headhertz*.  
420 Furthermore, consistent with the Google-imposed link requirements outlined in footnote 18, the  
421 firm creates four different landing pages, each with different content. The first Sitelink is a direct  
422 hyperlink to a webpage that is devoted to providing detailed information about the boxed warning  
423 on the potential for brain swelling. The second and third Sitelinks are direct hyperlinks to  
424 webpages that are each devoted to a discussion of the specific warning conveyed within the  
425 descriptions under these Sitelinks (i.e., a potentially fatal drug reaction and a life-threatening drop  
426 in heart rate). The fourth Sitelink is a direct hyperlink to the “Important Safety Information”  
427 webpage (within the product website) that is devoted to providing comprehensive risk information  
428 about *Headhertz*. The firm conveys risk information within the sponsored link format in a  
429 comparable manner to the benefit information. See example 2C in section VI in this draft  
430 guidance for further considerations on the inclusion of other product information for *Headhertz*  
431 within this sponsored link format.

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please refer to Google’s website for more specific information on its advertising policies. See *Sitelink extensions* available at <https://support.google.com/adwordspolicy/answer/1054210> and *Show additional links below your ad text* available at <https://support.google.com/adwords/answer/2375416>.

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**VI. RECOMMENDATIONS FOR THE INCLUSION OF OTHER PRODUCT INFORMATION ON INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE LIMITATIONS**

This section of the draft guidance provides additional recommendations regarding the inclusion of other product information (including certain required product information other than risk/benefit information, as applicable) on Internet/social media platforms with character space limitations. In addition to including both benefit and risk information within a character-space-limited communication, there may be other applicable legal requirements to consider.

In communicating product information on Internet/social media platforms associated with character space limitations, firms should consider the following:

- Sections 502(e), (n), and (r) of the FD&C Act (21 USC 352(e), (n), and (r)) require that the established name accompany the trade or brand name in labeling and in prescription drug and restricted-device advertising. Drug regulations specifically require that the established name be in direct conjunction with the proprietary name or designation (21 CFR 201.10(g)(1) and 202.1(b)(1)).<sup>19</sup>
- The drug regulations also stipulate that advertisements shall prominently display the name of at least one specific dosage form and have the quantitative ingredient information required by section 502(n) of the FD&C Act in direct conjunction with such display. If other dosage forms are listed in the advertisement, the quantitative ingredient information for such dosage forms shall appear in direct conjunction and in equal prominence with the most prominent listing of the names of such dosage forms (21 CFR 202.1(d)(2)).

With regard to the above regulatory provisions when using Internet/social media platforms with character space limitations, the Agency does not intend to object where the following approaches are used:

- Firms should communicate both the proprietary (trade or brand) name and established name (for drugs, often referred to as the generic name) within the character-space-limited communication. The generic name of the product should be listed directly to the right of, or directly below, the brand name.
- On the landing page associated with each hyperlink provided in the character-space-limited communication, firms should again communicate both the brand and established names as recommended in the preceding bullet. In addition, for prescription drugs, firms should

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<sup>19</sup> FDA has developed separate guidance that addresses product name placement and size in promotion. See the draft guidance *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling* available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070076.pdf>.



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471 prominently display at least one dosage form and quantitative ingredient information in direct  
472 conjunction with the brand and established names.

473  
474 In addition, the Agency believes that common abbreviations (including scientific and medical  
475 abbreviations), punctuation marks, and other symbols may, in many cases, reasonably be used to  
476 help address character space constraints. The following examples illustrate instances where the  
477 Agency does not intend to object to such usage:

- 478
- 479 • Commonly recognized linguistic symbols may be substituted for words. For example, the  
480 ampersand symbol (&) may be used in place of the word *and*.
  - 481
  - 482 • Punctuation marks may be used to help with the presentation of information. For example,  
483 dashes may be used to help separate benefit and risk information.
  - 484
  - 485 • A scientific abbreviation may be used to denote a chemical ingredient name (e.g., “HCl” for  
486 hydrochloride; “HBr” for hydrobromide).

487  
488 **Example 1C** (continued from example 1B): A firm is considering promotion of its prescription  
489 drug *NoFocus* on Twitter, which is limited to 140 character spaces per message or tweet. *NoFocus*  
490 is indicated for mild to moderate memory loss. There are no boxed or other warnings and no  
491 known fatal or life-threatening risks included in the PI for *NoFocus*. The most serious precaution  
492 associated with *NoFocus* is that it may cause seizures in patients with a seizure disorder. The  
493 FDA-approved name is *NoFocus (rememberine hydrochloride) Capsules*, and *NoFocus* is  
494 available as 200mg capsules. In addition to taking into consideration factors for communicating  
495 benefit and risk information within the character-space-limited communication as described in  
496 sections IV and V, the firm should also communicate the brand and established names within the  
497 tweet.

498  
499 The firm considers including the following product information, together with benefit and risk  
500 information about *NoFocus*, within the tweet:

501  
502 NoFocus (rememberine HCl) for mild to moderate memory loss-May cause seizures in  
503 patients with a seizure disorder [www.nofocus.com/risk](http://www.nofocus.com/risk) [134/140]

504  
505 In the above example, the brand and established names are communicated together within the  
506 tweet. Note that the firm uses the abbreviation *HCl* in place of *hydrochloride* within the  
507 established name presentation. The firm uses a dash with no additional spaces to separate the  
508 benefit and risk information. As specified in example 1B, the firm includes a direct hyperlink to  
509 the “Important Safety Information” webpage (within the product website) that is devoted to  
510 providing comprehensive risk information about *NoFocus*. At the top of the landing page, the firm  
511 again communicates the brand and established names together with the dosage form and  
512 quantitative information in direct conjunction as follows: NoFocus (rememberine hydrochloride)

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513 200mg Capsules. FDA would not intend to object to this tweet for *NoFocus*, as described in  
514 totality in examples 1A, 1B, and 1C.

515  
516 **Example 2C** (continued from example 2B): A firm is considering promotion of its prescription  
517 drug *Headhurtz* using Google’s Sitelinks. *Headhurtz* is indicated for severe headache associated  
518 with traumatic brain injury. The PI for *Headhurtz* includes a boxed warning about the potential for  
519 brain swelling and warnings about a potentially fatal drug reaction and a drop in heart rate that  
520 may be life-threatening. The FDA-approved name is *Headhurtz (ouchafol) Tablets*, and  
521 *Headhurtz* is available as 200mg tablets. In addition to taking into consideration factors for  
522 communicating benefit and risk information within the character-space-limited communication as  
523 described in sections IV and V, the firm should also communicate the brand and established names  
524 within the sponsored link format.

525  
526 The firm considers including the following product information, together with benefit and risk  
527 information about *Headhurtz*, within the sponsored link format:

528  
529       Headhurtz (ouchafol) [20/25]  
530       [www.headhurtz.com](http://www.headhurtz.com) [17/35]  
531       For severe headache from traumatic brain injury [47/70]  
532       Boxed warning [13/25]                               Warning [7/25]  
533       Potential for brain swelling [28/35]               Potentially fatal drug reaction [31/35]  
534       Warning [7/25]                                       Risk information [16/25]  
535       Life-threatening drop in heart rate [35/35]       Important safety information [28/35]

536  
537 In the above example, the brand and established names are communicated together within the  
538 sponsored link format. As specified in example 2B, consistent with the Google-imposed link  
539 requirements outlined in footnote 18, the firm creates four different landing pages, each with  
540 different content, to convey risk information for *Headhurtz*. At the top of each of these landing  
541 pages, the firm again communicates the brand and established names together with the dosage  
542 form and quantitative information in direct conjunction as follows: Headhurtz (ouchafol) 200mg  
543 Tablets. FDA would not intend to object to this sponsored link format for *Headhurtz*, as described  
544 in totality in examples 2A, 2B, and 2C.