
Guidance for Industry

“Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms

DRAFT GUIDANCE

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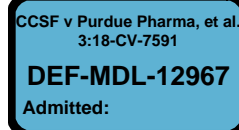
**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
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1 **Guidance for Industry**
2 **“Help-Seeking” and Other Disease Awareness Communications**
3 **by or on Behalf of Drug and Device Firms**
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5

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7 This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s) current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

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16
17 **I. INTRODUCTION**
18

19 The purpose of this document is to provide guidance to industry regarding so-called “help-
20 seeking” and other disease awareness communications, including a description of the specific
21 characteristics of communications that fall into this category. Disease awareness
22 communications are communications disseminated to consumers or health care practitioners that
23 discuss a particular disease or health condition, but do not mention any specific drug or device or
24 make any representation or suggestion concerning a particular drug or device. Help-seeking
25 communications are disease awareness communications directed at consumers. FDA believes
26 that disease awareness communications can provide important health information to consumers
27 and health care practitioners, and can encourage consumers to seek, and health care practitioners
28 to provide, appropriate treatment. This is particularly important for under-diagnosed, under-
29 treated health conditions, such as depression, hyperlipidemia, hypertension, osteoporosis, and
30 diabetes.
31

32 Unlike drug and device promotional labeling and prescription drug and restricted device
33 advertising, disease awareness communications are not subject to the requirements of the Federal
34 Food, Drug, and Cosmetic Act (the act) and FDA regulations. FDA recognizes the importance of
35 distinguishing between communications that are under FDA jurisdiction and those that are not.
36

37 FDA’s guidance documents, including this guidance, do not establish legally enforceable
38 responsibilities. Instead, guidances describe the agency’s current thinking on a topic and should
39 be viewed only as recommendations, unless specific regulatory or statutory requirements are
40 cited. The use of the word *should* in agency guidances means that something is suggested or
41 recommended, but not required.

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42 **II. FDA AUTHORITY OVER DRUG/DEVICE LABELING AND ADVERTISING**

43
44 FDA regulates the manufacture, sale, and distribution of drugs and devices in the United States
45 under the authority of the act. This authority includes oversight of promotional labeling for all
46 drugs and devices and advertising for prescription drugs and restricted devices. (21 U.S.C.
47 502(a), (n), (q), (r).)¹

48
49 The act defines “label” to mean “a display of written, printed, or graphic matter upon the
50 immediate container of any article . . .” (21 U.S.C. 321(k).) “Labeling” means “all labels and
51 other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers,
52 or (2) accompanying such article.” (21 U.S.C. 321(m).) According to *Kordel v. United States*,
53 335 U.S. 345 (1948), the language “accompanying such article” in the “labeling” definition
54 includes what supplements or explains an article, “in the manner that a committee report of the
55 Congress accompanies a bill. No physical attachment one to the other is necessary. It is the
56 textual relationship that is significant . . .” FDA regulations thus define as “labeling” a wide
57 variety of written, printed, or graphic matter that bears a textual relationship with a drug or
58 device. (See 21 CFR 202.1(l)(2).)

59
60 FDA generally recognizes two types of labeling for drugs and devices: FDA-approved labeling
61 and promotional labeling. FDA-approved labeling is prepared in the first instance by the sponsor
62 and then reviewed by the agency as part of the new drug application (NDA), biologics license
63 application (BLA) or premarket approval application (PMA) review. (21 CFR 314.50(c)(2),
64 601.2(a), and 814.20(b)(10).) For prescription products, the FDA-approved labeling must be
65 included in or within the package from which the drug or device is to be dispensed, or else the
66 product is deemed misbranded on the ground that it lacks adequate directions for use. (21 U.S.C.
67 352(f)(1); 21 CFR 201.100(c)(1) and 801.109(c).) Promotional labeling is generally any labeling
68 other than the FDA-approved labeling. For a prescription drug or device to comply with the act’s
69 requirement of adequate directions for use (21 U.S.C. 352(f)(1)), its labeling must contain,
70 among other information, information addressing product hazards and other risk information, as
71 specified in FDA regulations. (21 CFR 201.100(d)(1) & (3) and 801.109(d).)

72
73 Advertising² for prescription drugs and restricted devices is also subject to requirements under
74 the act for the disclosure of risk and other information. Advertisements for prescription drugs
75 must include, among other things, “information in brief summary relating to side effects,
76 contraindications, and effectiveness,” as specified in FDA regulations. (21 U.S.C. 352(n); see
77 also 21 CFR 202.1.) Advertisements for restricted devices must include “a brief statement of the
78 intended uses of the device and relevant warnings, precautions, side effects, and

¹ FDA has authority over promotional labeling and advertising for prescription drugs intended for human use. (21 U.S.C. 352(a) and (n).) FDA also has authority over promotional labeling for all devices. (21 U.S.C. 352(a).) The agency’s authority over device advertising only extends to restricted devices. (21 U.S.C. 352(q) and (r).) Other device advertising is regulated by the Federal Trade Commission (FTC). (15 U.S.C. 52.) See also 36 FR 18539; Sept. 16, 1971.

² The act does not specifically define “advertising” or “advertisement.” According to FDA regulations (21 CFR 202.1(l)(1)), “Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.”

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79 contraindications” (21 U.S.C. 352(r).) Both prescription drug and restricted device
80 advertisements also must not be false or misleading. (21 U.S.C. 352(q)(1) & 321(n); 21 CFR
81 202.1(e)(5).)

82
83 In contrast to product advertisements and promotional labeling pieces, “reminder” promotion³ is
84 exempted by regulation from the requirements under the act for the disclosure of risk
85 information. (21 CFR 200.200, 201.100(f), 202.1(e)(2)(i), 801.109(d).) Similarly, an FDA
86 regulation restricting promotion of investigational new drugs provides that a manufacturer may
87 “disseminat[e] . . . scientific findings in scientific or lay media” without engaging in promotional
88 activity, but promotional claims of safety or effectiveness for a use for which the product is
89 under investigation are subject to FDA regulation as advertising or labeling. (21 CFR 312.7(a).)

90
91

92 III. DISEASE AWARENESS COMMUNICATIONS BY OR ON BEHALF OF DRUG 93 AND DEVICE FIRMS

94

95 A. Characteristics of Disease Awareness Communications

96

97 FDA will treat as a disease awareness communications any communications by or on behalf of a
98 manufacturer, distributor, or retailer of a drug or device that:

99

- 100 • discuss a disease or health condition;
- 101 • if consumer-directed, advise the audience to “see your doctor” for possible diagnosis
102 and/or treatment;
- 103 • if aimed at health care practitioners, encourage awareness of signs of the particular
104 disease or health condition, or otherwise provide information to assist in the diagnosis of
105 the particular disease or health condition;
- 106 • do not mention a particular drug or device; and
- 107 • do not include any representation or suggestion relating to a particular drug or device.

108

109 This kind of communication constitutes neither labeling nor advertising and is, therefore, not
110 subject to the requirements for the disclosure of risk information and other requirements under
111 the act. As discussed in greater detail below in section IV, however, there are circumstances in
112 which FDA will treat as labeling or advertising a supposed disease awareness communication
113 that is combined with reminder advertising or labeling. In this situation, or in other situations
114 where a supposed disease awareness communication is determined to, by implication, identify a
115 particular drug or device, the communication can be considered labeling or advertising and can
116 therefore be subject to regulation by FDA.

117

³ According to FDA regulations (21 CFR 200.200(a)(1) and 801.109(d)), reminder labeling is labeling that calls attention to the name of a drug or device but does not, among other things, include indications, dosage recommendations, or other representations or suggestions concerning safety or effectiveness. Similarly, “Reminder advertisements are those which call attention to the name of the drug product but do not include indications or dosage recommendations for use of the drug product.” (21 CFR 202.1(e)(2)(i).)

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118 Where a company is the only manufacturer of a commercially available medical product for a
119 particular disease or health condition or where a company only manufactures one product, that
120 company is not automatically disqualified from disseminating communications that discuss a
121 disease or health condition relating to that product. If, however, FDA determines that a supposed
122 disease awareness communication impliedly identifies a particular drug or device, which may be
123 the case when a communication relates to a drug or device that is the only drug or device in its
124 diagnostic or therapeutic class or the only product manufactured by a company,⁴ then the agency
125 may treat the communication as labeling or advertising under the act.

B. Disease Awareness Communications Directed at Health Care Practitioners

127
128
129 As noted above in section III.A, disease awareness communications can be directed at either
130 consumers or health care practitioners. In this section, FDA is providing examples of materials
131 that drug and device firms might disseminate to health care practitioners as disease awareness
132 communications to help clarify when those communications would not be considered advertising
133 or labeling subject to the requirements of the act and of FDA regulations.

- 134
135 1. Recommendations for screening and treatment of a disease or health condition in
136 primary care settings (e.g., National Institute of Mental Health screening and
137 treatment recommendations for depression in men in primary care settings)
- 138
139 2. Counseling recommendations for health care practitioners with respect to a
140 particular disease or health condition (e.g., Alliance for Cervical Cancer
141 Prevention cervical cancer prevention "fact sheet")

142
143 Although the examples above involve materials prepared and disseminated by or on behalf of a
144 government agency and an educational organization, respectively, FDA believes the same types
145 of communications may be prepared and/or disseminated by or on behalf of drug and device
146 firms.

147
148 If communications such as those described above as examples are not disseminated by or on
149 behalf of a drug or device firm, they would be outside of FDA's labeling and advertising
150 jurisdiction, whether or not they meet the criteria for disease awareness communications set forth
151 in section III.A of this guidance document.

C. FDA Recommendations for the Content of Disease Awareness Communications

⁴ In either of these situations, the mere appearance of the company's name in conjunction with a disease reference could trigger the act's advertising or labeling requirements, depending on the overall meaning and context of the communication. Similarly, depending on meaning and context, FDA might have jurisdiction over statements regarding the benefits of a product class to which a company's drug or device belonged, even if the communication in which the statements occurred did not mention any specific product. Where FDA does not have jurisdiction, the agency may nevertheless take appropriate action (e.g., issuing a public statement or referring the matter to the FTC) where we believe a communication is false or misleading, or includes an unbalanced presentation of the benefits and risks of a particular product class.

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156 FDA encourages drug and device manufacturers to develop disease awareness communications,
157 particularly for diseases and health conditions of particular public health importance. FDA
158 particularly encourages the development of disease awareness communications for serious or
159 life-threatening diseases or health conditions that are under-diagnosed or under-treated.

160
161 FDA believes that disease awareness communications should be designed with certain principles
162 in mind.⁵ In general, disease awareness communications should:

- 163
- 164 • be disease- or health condition-specific;
 - 165 • enhance consumer or health care practitioner education;
 - 166 • be clear and accurate;
 - 167 • identify the population at risk or affected by the disease or health condition; and
 - 168 • contain a responsible public health message (i.e., information on the prevention,
169 diagnosis or treatment of a disease or condition).

170
171 In addition, disease awareness communications aimed at consumers should

- 172
- 173 • refer consumers to a qualified health care practitioner for more information; and
 - 174 • avoid encouraging self-diagnosis and self-treatment.

175
176

IV. COMBINING DISEASE AWARENESS COMMUNICATIONS WITH 178 REMINDER OR PRODUCT CLAIM PROMOTION

179
180 As discussed above, a supposed disease awareness communication disseminated by or on behalf
181 of a drug or device manufacturer, packer, or distributor can be subject to regulation by FDA as
182 promotional labeling or advertising if it mentions a specific drug or device or contains a
183 representation or suggestion concerning a specific drug or device. This section focuses on one
184 specific situation in which a supposed disease awareness communication may be treated by FDA
185 as labeling or advertising: when the communication is presented in combination with reminder
186 promotion or product claim promotion in a way that causes the audience to perceive the two
187 pieces as one advertisement or promotional labeling piece.

188
189 For example, some drug firms have broadcast help-seeking advertisements in combination with
190 perceptually similar reminder advertisements, separated only by a brief period containing
191 unrelated intervening matter. When considered in isolation, the help-seeking advertisement
192 conveys the message, “There is help for a particular medical condition; see your doctor.” As
193 discussed above, this advertisement would be neither labeling nor advertising and thus would not
194 be subject to the requirements under the act for the disclosure of risk and other information. The
195 perceptually similar reminder advertisement, by itself, conveys the message, “This specific
196 product is available; see your doctor.” As discussed above, this advertisement would be
197 exempted by regulation from the requirements for disclosure of risk or other information.

198

⁵ These principles are taken from the American Medical Association policy on Direct-to-Consumer Advertising (DTCA) of Prescription Drugs (H-105.988).

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199 Together, however, these two advertisements communicate information about a treatable disease
200 or health condition and the name of a product approved for treatment of a disease or health
201 condition, and effectively constitute an advertisement that communicates a product's indication
202 and efficacy for a certain medical condition without providing risk and other information. If a
203 disease awareness or help-seeking piece and a reminder advertisement are presented in a manner
204 that causes their messages to be linked together by the audience, the failure of the combined
205 communication to include the risk and other information required under the act and FDA
206 regulations would cause the advertised product to be misbranded.

207
208 Similarly, a supposed disease awareness communication could be properly treated as advertising
209 or promotional labeling if presented in combination with a product claim advertisement or
210 promotional labeling piece in a manner that causes the pieces' messages to be linked together by
211 the audience. In such a case, the combined communication would also communicate a particular
212 product's indication and efficacy for a certain medical condition. If the combined
213 communication does not comply with the act and FDA's advertising or labeling regulations, the
214 communication would cause the promoted product to be misbranded.

215
216 Psychology and marketing research suggests that the greater the perceptual similarity between
217 disease awareness communications and reminder or product claim promotions (i.e., similarities
218 in terms of their themes, such as story lines, or other presentation elements, such as colors, logos,
219 tag lines, graphics, etc.), and the closer they are presented physically or in time to one another,
220 the more likely it is that the separate messages contained in the two pieces will be remembered
221 together in memory as one entity.⁶ Perceptual similarity is an important factor because research
222 indicates that pieces are most likely to be linked together in memory when they have prominent
223 cues in common, such as distinctive visual elements, a common narrator or background music, or
224 a common story line.⁷

225
226 Perceptually similar communications or promotional pieces that appear closely in time or in
227 close physical proximity have a repetitive effect on each other. Repetition of information helps
228 solidify and reinforce it in memory;⁸ thus, disseminating pieces with similar presentation
229 elements will increase the likelihood the messages from each piece will be remembered and that
230 mental links between the pieces will be formed and strengthened. For example, a help-seeking
231 communication preceding a perceptually similar reminder advertisement (or vice-versa) is likely
232 to reinforce, through repetition, the images and message encoded in memory.⁹ The practical

⁶ Fiske, S.T. and Neuberg, S.L. (1990). A continuum of impression formation, from category-based to individuating processes: Influences of information and motivation on attention and interpretation. In M.P. Zanna (Ed.), Advances in Experimental Social Psychology (Vol. 23), New York: Academic Press (hereinafter "Fiske & Neuberg"); Higgins, E.T. and Bargh, J.A. (1987). Social cognition and social perception. In M.R. Rosenweig & L.W. Porter (Eds.), Annual Review of Psychology, 38, 369-425. (hereinafter "Higgins & Bargh"); Baeyens, F., Crombez, G., and Eelen, P. (1988). Once in contact, always in contact: Evaluative conditioning is resistant to extinction. Advanced Behavioral Research and Therapy, 10, 179-199.

⁷ Fiske & Neuberg; Higgins & Bargh.

⁸ Fiske, S.T. and Taylor, S.E. (1991). Social Cognition. New York: McGraw Hill.

⁹ Zhao, X. (1997). Clutter and serial order redefined and retested. Journal of Advertising Research, September/October, 57-73;

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233 result of this process is that the audience will perceive these as components of one complete
234 promotional piece. The more similar disease awareness communications and reminder
235 promotional pieces or product claim promotional pieces are in terms of their presentation
236 elements and the closer to one another they are presented physically or in time, the more likely it
237 is that the key messages in the two pieces will be associated in memory.
238

239 In determining whether two communications together qualify as promotional labeling or
240 advertising, and therefore must comply with the act and FDA regulations relating to advertising
241 or labeling, FDA considers the following factors:
242

- 243 • Are the pieces perceptually distinct in use of graphic, visual, thematic, or other
244 presentation elements?
- 245 • Are the pieces presented in close physical or temporal proximity?
246

247 Of these two factors, FDA considers the determinant issue to be whether the pieces are
248 perceptually distinct. Thus, FDA recommends that manufacturers, packers, and distributors
249 ensure that their disease awareness communications and reminder promotional pieces or product
250 claim promotional pieces are sufficiently distinctive in terms of their thematic, graphic, visual
251 and other presentation elements so that they will not be perceived as a single promotional piece
252 that includes both a product name and a use, and is thus subject to the requirements for
253 “labeling” or “advertising” mandated by the act and regulations. With regard to the second
254 factor, FDA recognizes that “close physical or temporal proximity” is difficult to define precisely
255 and is unaware of any data that help establish specific criteria. FDA requests comment on
256 whether such data do exist or, in the absence of data, whether there would be utility in trying to
257 develop specific criteria. For example, the agency could consider two communications that are
258 not perceptually distinct to be in “close temporal proximity” in a broadcast advertisement if they
259 were presented within the same 15 minutes of a one half hour program or the same half hour of a
260 one hour program. Similarly, the agency requests comment on how “proximity” could be best
261 considered for two communications that are not perceptually distinct if they were presented in
262 the same publication (i.e., magazine, newspaper).