
Guidance for Industry

Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

DRAFT GUIDANCE

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Center for Veterinary Medicine (CVM)
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Guidance for Industry

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This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA) current thinking on this topic.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This draft guidance is intended to describe the Food and Drug Administration’s (FDA or Agency) current thinking about how manufacturers and distributors (firms) of prescription human and animal drug products (drugs) and medical devices (devices) can respond to unsolicited requests for information about unapproved or uncleared indications or conditions of use (off-label information) related to their FDA-approved or cleared products.^{1,2} This draft guidance updates and clarifies FDA’s policies on unsolicited requests for off-label information, including those that firms may encounter through emerging electronic media.

¹ This draft guidance has been prepared by the Office of Prescription Drug Products (OPDP) in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Center for Veterinary Medicine (CVM).

² The recommendations in this draft guidance also apply to biological products that are approved for marketing under section 351 of the Public Health Service Act (PHS Act).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. (See PHS Act section 351(j), 42 U.S.C. 262(j).)

In addition, the term “approved or cleared product” in this draft guidance encompasses devices that are legally marketed for a specific intended use without an individual product approval or substantial equivalence determination (clearance). This includes class I and class II devices marketed for uses that make them exempt from premarket notification, in accordance with sections 510(l) or (m) of the FD&C Act (21 U.S.C. 360(l) & (m)). As a result, with regard to such products, a request for “off-label information” refers to any request for information regarding a new use for which approval or clearance would be required. This draft guidance does not address devices solely intended for use in animals.

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26 This draft guidance does not address requests for information about approved or cleared
27 indications or conditions of use (on-label information) for FDA-regulated medical products. It
28 also does not address requests for information about medical products that are not currently
29 approved or cleared for any purpose.

30
31 FDA’s guidance documents, including this draft guidance, do not establish legally enforceable
32 rights or responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and
33 should be viewed only as recommendations, unless specific regulatory or statutory requirements
34 are cited. The use of the word *should* in Agency guidances means that something is suggested or
35 recommended, but not required.

36
37
38 **II. BACKGROUND**

39
40 The Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's implementing regulations
41 prohibit manufacturers and distributors (firms) from introducing new drugs, new animal drugs, and
42 most Class III medical devices into interstate commerce for any intended use that FDA has not
43 determined to be safe and effective. The FD&C Act and FDA’s implementing regulations also
44 prohibit device firms subject to premarket notification requirements under section 510(k), which
45 includes most class II and some class I devices, from introducing such devices into interstate
46 commerce for any intended use that is outside FDA’s substantial equivalence determination
47 (clearance) for such devices.³ Statements that promote a drug or medical device for uses other
48 than those approved or cleared by FDA may be used as evidence of a new intended use.
49 Introducing a product into commerce for such a new intended use without FDA approval or
50 clearance would, under these requirements, generally violate the law. However, once a drug or
51 medical device has been approved or cleared by FDA, generally, health care professionals can
52 lawfully use or prescribe that product for uses or treatment indications that are not included in the
53 product's approved labeling⁴ (or, in the case of a medical device cleared under the 510(k) process,
54 in the product's statement of intended uses). FDA recognizes that these off-label uses or treatment
55 regimens may be important therapeutic options and may even constitute a medically recognized
56 standard of care.

57
58 Scientific or medical departments within drug or medical device firms often maintain a large body
59 of information about their products. This information typically includes data and other
60 information consistent with the approved or cleared indications or conditions of use for their
61 products, but may also include off-label information for their products. As noted, although
62 dissemination of off-label information can be used as evidence of new intended uses for products
63 in distribution, such information may also be of use to individuals seeking information about a

³ See e.g., sections 505(a), 501(a), 301(d), 501(f)(1)(B) and 502(o) of the FD&C Act; 21 U.S.C. 355(a), 351(a), 331(d), 351(f)(1)(B) and 352(o).

⁴ See sections 512(a)(4) and (a)(5) of the FD&C Act and this Agency’s regulations at 21 CFR part 530 for specific provisions related to the off-label (or extra-label) use of approved animal and human drugs in animals.

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64 medical product for themselves, patients, family members, or friends. These individuals
65 sometimes submit non-public requests for off-label information directly and privately to firms.
66

67 The rapid growth of the Internet, including social media tools and other emerging technologies,
68 has made it easier for both consumers and health care professionals to quickly seek information
69 about medical conditions and treatments.⁵ Many firms have also used emerging electronic media
70 to disseminate product information. As a result, firms may encounter requests for off-label
71 information about their products through product websites, discussion boards, chat rooms, or other
72 public electronic forums that they maintain and over which they have full control. In addition,
73 third-party sites (i.e., websites and other venues that are either entirely independent of a firm’s
74 control and influence or not fully controlled by a firm) also may reveal questions about off-label
75 uses of a firm’s products. These questions about off-label uses are typically directed to users of
76 the site at large, rather than directly and privately to firms. Such posted information is likely to be
77 available to a much broader audience than just the original requester, especially because
78 communication threads (i.e., questions and replies) are often available for an indefinite period of
79 time.

80
81 This draft guidance provides FDA’s recommendations to firms wishing to respond to unsolicited
82 requests for off-label information, including both requests made directly and privately to firms and
83 requests made in public forums, including through emerging electronic media. FDA recognizes
84 that firms are capable of responding to requests about their own named products in a truthful, non-
85 misleading, and accurate manner. Furthermore, as these firms are regulated by FDA and have
86 robust and current information about their products, FDA recognizes that it can be in the best
87 interest of public health for a firm to respond to unsolicited requests for information about off-label
88 uses of the firm’s products that are addressed to a public forum, as other participants in the forum
89 who offer responses may not provide or have access to the most accurate and up-to-date
90 information about the firm’s products.

91
92 If a firm responds to unsolicited requests for off-label information in the manner described in this
93 draft guidance, FDA does not intend to use such responses as evidence of the firm’s intent that the
94 product be used for an unapproved or uncleared use. Such responses would also not be expected
95 to comply with the disclosure requirements related to promotional labeling and advertising. Firms
96 may choose to respond to unsolicited requests for information about off-label uses of their
97 approved or cleared products in a manner other than that recommended in this draft guidance.
98 Such activity would not constitute a per se violation of the law, but could potentially be introduced
99 as evidence of a new intended use.⁶

⁵ For example, the public is able to obtain information on certain clinical trial results from www.ClinicalTrials.gov. This may include information related to off-label uses. This information may generate questions directly to a firm.

⁶ This draft guidance is not intended to suggest that receiving an unsolicited request is the only circumstance in which a firm can disseminate information about unapproved uses of its FDA-regulated products without such dissemination being used as evidence of the firm’s intent that the product be used for an unapproved use. For example, FDA has developed separate guidance that addresses manufacturer-initiated distribution of reprints regarding off-label uses. See *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference*

100 **III. DETERMINING WHETHER A REQUEST IS UNSOLICITED OR SOLICITED**

101
102 This draft guidance addresses how to respond to *unsolicited requests* for off-label information
103 about drugs and medical devices. To illustrate the difference between unsolicited and solicited
104 requests, this section describes these two categories of requests and presents a number of examples
105 of both types of requests.

106
107 **A. Unsolicited Requests**

108
109 Unsolicited requests are those initiated by persons or entities that are completely independent of
110 the relevant firm. (This may include many health care professionals, health care organizations,
111 members of the academic community, and formulary committees, as well as consumers such as
112 patients and caregivers). Requests that are prompted in any way by a manufacturer or its
113 representatives are not unsolicited requests. Two types of unsolicited requests are addressed in this
114 draft guidance: non-public unsolicited requests and public unsolicited requests. Responses to
115 unsolicited requests can likewise be non-public (private) or public.

- 116
117 • Non-public unsolicited requests

118
119 A non-public unsolicited request is an unsolicited request that is directed privately to a firm using a
120 one-on-one communication approach.

121
122 *Example 1:* An individual calls or e-mails the medical information staff at a firm seeking
123 information about an off-label use. In this case, neither the request nor the response would be
124 visible to the public.

- 125
126 • Public unsolicited requests

127
128 A public unsolicited request is an unsolicited request made in a public forum, whether directed to a
129 firm specifically or to a forum at large.

130
131 *Example 2:* During a live presentation, an individual asks a question, directed to a firm's
132 representative but heard by other attendees, regarding off-label use of a specific product. This
133 request is a public request. Similarly, a response by the firm that is conveyed to the same audience
134 as the original question would be considered a *public response*.

135
136 *Example 3:* An individual posts a question about off-label use of a specific product on a firm-
137 controlled website (or a third-party discussion forum) that is visible to a broad audience. The
138 request could be directed to a firm specifically or posed to users of a discussion forum at large.

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139 This request is a public online request. Similarly, a response by the firm that is visible to the same
140 audience as the original question would be considered a *public online response*.

141

142 **B. Solicited Requests**

143

144 FDA considers requests for off-label information that are prompted in any way by a manufacturer
145 or its representatives to be solicited. Such solicited requests may be considered evidence of a
146 firm’s intent that a drug or medical device be used for a use other than that specifically approved
147 or cleared by FDA. Although not exhaustive, the following examples illustrate what FDA
148 generally considers to be solicited requests for off-label information⁷:

149

150 *Example 4:* If a firm’s sales representative mentions a use of a product that is not reflected in the
151 product’s approved labeling and invites a health care professional to request more information,
152 resulting requests would be considered solicited requests.

153

154 *Example 5:* If a representative of a firm, such as a medical science liaison or paid speaker (e.g.,
155 key opinion leader), presents off-label use data at a company-sponsored promotional event (e.g., a
156 dinner) and attendees then ask or submit requests for more information, these requests would be
157 considered solicited requests.

158

159 *Example 6:* If a firm issues to health care professionals business reply cards that are intended for
160 use in requesting off-label information, presents statements or contact information in promotional
161 pieces in a manner that solicits requests for off-label medical or scientific information (e.g.,
162 “Product X continues to be evaluated in more than 50 trials in a broad range of conditions and
163 patients” and “Call 1-800-... for more information”), or displays a commercial exhibit panel
164 suggesting a new indication (e.g., a sign that reads “Coming Soon, a new use for Product X”),
165 requests made in response to these types of prompts would be considered solicited requests.

166

167 *Example 7:* If a firm provides a phone number, e-mail address, uniform resource locator (URL), or
168 username that is a word, alpha phrase, or alpha representation implying the availability of off-label
169 information for its product, requests using this phone number, e-mail address, URL, or username
170 would be considered solicited requests.

171

172 *Example 8:* A firm asks or otherwise encourages users to post videos about their own uses of its
173 product on third-party video-sharing sites (e.g., YouTube), which may result in video postings
174 about an off-label use of its product. If the firm’s initial request for posting of videos results in any
175 questions about off-label uses, or if any off-label video posting made in response to the firm’s
176 encouragement of video postings results in questions about the product’s off-label use, these
177 questions would be considered solicited requests.

⁷ The focus of this draft guidance is unsolicited requests for off-label information, not compliance with provisions of FDA’s advertising and labeling regulations for drugs. We note, however, that in some of the following examples, a firm’s activities that serve to solicit the requests for off-label information may themselves give rise to specific regulatory violations.

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178 *Example 9:* If a firm sends out packets of information to known bloggers or online consumer
179 reviewers and encourages them to write about an off-label use of its product on third-party sites
180 and this then provokes a discussion about that off-label use, any requests inquiring about the
181 product's off-label use as a result of these blogs, whether posted as comments to the third-party
182 site or directed to the firm, would be considered solicited requests.
183

184 *Example 10:* If a firm announces results of a study via a microblogging service (e.g., Twitter) and
185 suggests that an off-label use of its product is safe and effective, any comments and requests
186 received as a result of the original message about the off-label use would be considered solicited
187 requests.
188

189 *Example 11:* If a firm sets up a website that enables viewers to read prepared standard responses
190 for the firm's products that are generated from prefixed pull-down menus naming various disease
191 states, including any standard responses related to off-label uses for the firm's product, resulting
192 requests for off-label information would be considered solicited. Moreover, if this website makes
193 it possible to use search terms to generate standard responses that go beyond the scope of the
194 product information being requested, including off-label use information, resulting requests for and
195 responses to such a search would be considered solicited requests.
196

197
198 **IV. OVERVIEW OF FDA'S POLICY ON RESPONDING TO UNSOLICITED**
199 **REQUESTS FOR OFF-LABEL INFORMATION**
200

201 FDA has long taken the position that firms can respond to unsolicited requests for information
202 about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-
203 promotional scientific or medical information that is responsive to the specific request, even if
204 responding to the request requires a firm to provide information on unapproved or uncleared
205 indications or conditions of use. If responses to unsolicited requests fall within these parameters,
206 FDA has not expected those responses to meet regulatory requirements for promotional labeling or
207 advertising and has not considered these responses as evidence of intended use. This draft
208 guidance sets forth FDA's current thinking on this topic, consistent with the Agency's past policy
209 statements about responding to unsolicited requests.^{8,9} Regardless of whether the initial

⁸ This policy was articulated in a letter to industry in 1982 and has been restated on many occasions. See *Position on the Concept of Solicited and Unsolicited Requests* (April 22, 1982) ("[T]he Division of Drug Advertising and Labeling will not regulate as labeling any and all unsolicited requests received from outside the company for information about a drug manufactured, distributed, or repacked by the company. These types of legitimate requests from scientists/individuals for drug information will be regarded and treated as a personal communication between the requestor and firm."); 59 Fed. Reg. 59820, 59823 (November 18, 1994) (stating that manufacturers may respond to unsolicited requests for information with "responsive, nonpromotional, balanced scientific information, which may include information on unapproved uses, without subjecting their products to regulation based on the information"). FDA's current views (expressed in this draft guidance) remain consistent with these past policy statements.

⁹ In addition, section 557(a) of the FD&C Act, which expired on September 30, 2006, provided that "nothing in section 551 [of the Act] shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner." 21 U.S.C.360aaa-6

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210 unsolicited request for off-label information was made in a non-public or public forum, a firm that
211 chooses to respond should provide the final response containing the requested off-label
212 information about its product only to the specific individual who requested the information as a
213 private, one-on-one communication.

214
215 Section V explains in detail FDA’s recommendations for firms that choose to respond to non-
216 public unsolicited requests for off-label information, and Section VI addresses FDA’s
217 recommendations for firms that choose to respond to public unsolicited requests for off-label
218 information, including those that are encountered through emerging electronic media.

219
220
221 **V. RESPONDING TO NON-PUBLIC UNSOLICITED REQUESTS FOR OFF-LABEL**
222 **INFORMATION DIRECTED TO DRUG OR MEDICAL DEVICE FIRMS**

223
224 This section of the draft guidance makes recommendations about responding to non-public
225 unsolicited requests for off-label information about prescription human and animal drugs (drugs)
226 and medical devices (devices) specifically directed to firms privately through one-on-one
227 communications. For example, an individual might call or correspond directly with a firm
228 concerning the use of its product for an unapproved or uncleared indication or condition of use.
229 The firm could receive the request by mail, e-mail, telephone, or through a firm-controlled website
230 that enables individuals to privately submit a request directly to the firm so that the request is *not*
231 available to the public.

232
233 FDA makes the following recommendations to a firm that is responding to a *non-public*
234 unsolicited request for off-label information about its product that was specifically directed to the
235 firm privately through a one-on-one communication.

- 236
237 1. Information distributed in response to an unsolicited request should be provided only to the
238 individual making the request directly to the firm as a private, one-on-one communication.
239
240 2. Information distributed in response to an unsolicited request should be tailored to answer only
241 the specific question(s) asked.

242
243 A firm should ensure that all pertinent background data are obtained to be able to determine what
244 information is being requested before providing a response. If an unsolicited question is broad in
245 nature, the firm should appropriately narrow the question. In other words, the level of specificity
246 of the question posed is important to ensure that the firm’s response is tailored to the request.

247
248 *Example 12:* An individual requests information on the use of a drug or device for one particular
249 disease or condition that is considered off-label for that drug or device (e.g., use of Drug X during
250 pregnancy in patients with diabetes). Generally, a firm should provide information pertaining only
251 to that disease or condition (i.e., the firm should provide a response tailored only to the use of Drug
252 X during pregnancy in patients with diabetes).

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253 However, if there is information about known or suspected *risks* associated with other diseases or
254 conditions that is also relevant to the disease or condition for which information was requested, the
255 firm should provide such information to ensure a complete and accurate presentation of the risk
256 issues associated with the requested use (e.g., Drug X is known to cause fetal harm when used in
257 pregnant patients with arthritis, and this risk information should be disclosed as part of the
258 response about use of Drug X during pregnancy in patients with diabetes).

259
260 3. Information distributed in response to an unsolicited request should be truthful, non-
261 misleading, accurate, and balanced.¹⁰
262

263 A response should provide non-biased information or data relating to the particular off-label use
264 that is the subject of the request, including applicable data that are not supportive or that cast doubt
265 on the safety or efficacy of that use. For example, when conclusions of articles or texts that are
266 disseminated have been specifically called into question by other articles or texts, a firm should
267 disseminate representative publications that reach contrary or different conclusions regarding the
268 use at issue. The response should include complete copies of scientific reprints, technical
269 literature, or other scientific and medical information responsive to the request, not just summary
270 documents or abstracts prepared by the firm. The response can include unpublished data on file if
271 they are responsive to the specific request (either supporting or casting doubt on the safety or
272 efficacy of the off-label use). However, to the greatest extent possible, a firm should rely on
273 published peer-reviewed journal articles, medical texts, or data derived from independent sources.
274 To the extent the response consists of published reprints from journals, those reprints should be
275 from journals that have a publicly stated policy, to which the organization adheres, of full
276 disclosure of any conflict of interest or biases for all authors, contributors, or editors associated
277 with the journal or organization.
278

279 4. Information distributed in response to an unsolicited request should be scientific in nature.
280

281 When responding to an unsolicited request for information, a firm should respond with material
282 that is scientific in tone and presentation. The material should not be promotional in tone or
283 presentation. Furthermore, the responsive material should not be distributed along with other
284 material or information that is promotional in nature or tone.
285

286 5. Responses to unsolicited requests for information should be generated by medical or scientific
287 personnel independent from sales or marketing departments.
288

289 FDA recommends that questions or requests about off-label uses be referred to the firm's medical
290 or scientific representative or department. FDA recommends that medical or scientific personnel
291 have specialized backgrounds in responding to unsolicited requests for information, including

¹⁰ Evaluating evidence of intended use may also involve considering the context in which manufacturer communication about an off-label use occurs. For this reason, FDA's recommendations in this draft guidance for responding to unsolicited requests for information by third parties are not identical to its recommendations regarding the spontaneous manufacturer-initiated activity of distributing reprints, as addressed in other FDA guidance.

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292 important training, such as appropriately narrowing questions, tailoring responses only to the
293 specific questions being asked, providing unbiased responses, and properly documenting
294 responses.

295
296 By contrast, because sales and marketing personnel are focused by training and experience on
297 promoting a firm's products, FDA recommends that sales and marketing personnel have no input
298 on the content of responses to unsolicited questions or requests for off-label information.
299

300 6. Information distributed in response to an unsolicited request should be accompanied by the
301 following:

- 302
- 303 • A copy of the FDA-required labeling, if any, for the product (e.g., FDA-approved package
304 insert and, if the response is for a consumer, FDA-approved patient labeling or, for new
305 animal drugs, FDA-approved client information sheet)
 - 306 • A prominent statement notifying the recipient that FDA has not approved or cleared the
307 product as safe and effective for the use addressed in the materials provided
 - 308 • A prominent statement disclosing the indication(s) for which FDA has approved or cleared
309 the product
 - 310 • A prominent statement providing all important safety information including, if applicable,
311 any boxed warning for the product
 - 312 • A complete list of references for all of the information disseminated in the response (e.g., a
313 bibliography of publications in peer-reviewed medical journals or in medical or scientific
314 texts; citations for data on file, for summary documents, or for abstracts)

315
316 7. A firm should maintain the following records:

- 317
- 318 • The nature of the request for information, including the name, address, and affiliation
319 of the requestor
 - 320 • Records regarding the information provided to the requestor
 - 321 • Any follow-up inquiries or questions from the requestor
- 322

323 If a firm responds to non-public unsolicited requests for off-label information in the manner
324 described above, FDA does not intend to use such responses as evidence of the firm's intent that
325 its product be used for an unapproved or uncleared use. Such responses also would not be
326 expected to comply with the disclosure requirements related to promotional labeling and
327 advertising.

328
329

330 **VI. RESPONDING TO PUBLIC UNSOLICITED REQUESTS FOR OFF-LABEL**
331 **INFORMATION, INCLUDING THOSE ENCOUNTERED THROUGH**
332 **EMERGING ELECTRONIC MEDIA BY DRUG OR MEDICAL DEVICE FIRMS**
333

334 This section of the draft guidance makes recommendations about responding to public unsolicited
335 requests for off-label information about prescription human and animal drugs (drugs) and medical
336 devices (devices), including those that are encountered through emerging electronic media.
337

338 The Internet has revolutionized communication, information-sharing, information exchange among
339 systems, and collaboration, enabling consumers to become more proactive about their health and
340 safety. Consequently, the Internet has become a widely used medium for manufacturers and
341 distributors of FDA-regulated medical products to disseminate information. The Internet has also
342 spawned a variety of social media tools that host online content primarily created and published by
343 users other than the intellectual property owner or product manufacturer. In some cases, this
344 online content may not be accurate. Because consumers increasingly use the Internet to search for
345 information about medical conditions and treatments, firms may receive public requests for off-
346 label information about their products through, for example, product websites, discussion boards,
347 chat rooms, or other public electronic forums that they maintain and over which they have full
348 control. Firms may also encounter requests for off-label information on third-party sites (i.e.,
349 websites and other venues that are either entirely independent of a firm’s control and influence or
350 not fully controlled by a firm). Questions about off-label use may be directed to the website users
351 at large, rather than specifically to a firm.
352

353 As previously stated in Section II, FDA recognizes that firms are capable of responding to requests
354 about their own named products in a truthful, non-misleading, and accurate manner. Moreover,
355 because firms usually have robust and current information about their products, it can be in the
356 best interest of public health for a firm to respond to unsolicited requests for information about off-
357 label uses of the firm’s products that are made in public forums, especially since other responders
358 may not provide or have access to the most accurate and up-to-date medical product information.
359

360 However, because product information posted on websites and other public electronic forums is
361 likely to be available to a broad audience and for an indefinite period of time, FDA is concerned
362 that firms may post detailed public online responses to questions about off-label uses of their
363 products in such a way that they are communicating unapproved or uncleared use information
364 about FDA-regulated medical products to individuals who have not requested such information. In
365 this circumstance, communications to persons who have not requested information may promote a
366 product for a use or condition for which FDA has not approved or cleared. FDA is also concerned
367 about the enduring nature of detailed public online responses to off-label questions because
368 specific drug or device information may become outdated (e.g., new risk information may become
369 available).
370

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371 FDA makes the following recommendations to a firm that chooses to respond to **public** unsolicited
372 requests for off-label information about its product(s), including those encountered through
373 emerging electronic media.

374
375 1. If a firm chooses to respond to public unsolicited requests for off-label information, the firm
376 should respond only when the request pertains specifically to its own named product (and is
377 not solely about a competitor’s product).

378
379 The level of specificity of the question posed in a public forum is important in determining the
380 appropriateness of a firm responding to the unsolicited request.

381
382 *Example 13:* An individual poses the specific question “Can Drug/Device X be used for Condition
383 Y” in a public forum (and this question is not prompted by or on behalf of the firm). It may be
384 appropriate for the firm to respond as outlined below because the question is unsolicited and
385 specific to the firm’s named drug or device.

386
387 However, if an individual poses the non-specific question “What drug/device can be used for
388 Condition Y” in a public communication thread and the firm manufactures or distributes
389 Drug/Device X, which is not FDA-approved or cleared for Condition Y, the firm should not
390 respond to the request because the question is **not** specific to Drug/Device X.

391
392 2. A firm’s **public** response to public unsolicited requests for off-label information about its
393 named product should be limited to providing the firm’s contact information and should **not**
394 include any off-label information.

- 395
- 396 • The firm’s public response should convey that the question pertains to an unapproved or
397 uncleared use of the product and state that individuals can contact the medical/scientific
398 representative or medical affairs department with the specific unsolicited request to obtain
399 more information.
 - 400 • The firm’s public response should provide specific contact information for the medical or
401 scientific personnel or department (e.g., e-mail address, telephone number, facsimile) so
402 that individuals can follow up independently with the firm to obtain specific information
403 about the off-label use of the product through a non-public, one-on-one communication.

404
405 After an individual has privately contacted a firm for more information regarding an off-label use
406 of the firm’s product, the firm should provide a detailed response and maintain records following
407 the parameters outlined in Section V of this draft guidance. Therefore, any substantive
408 communication about off-label uses for the product, in response to the original unsolicited off-
409 label question, should occur solely between the firm and the individual who made the request.
410 Regardless of the fact that the original, unsolicited off-label question may have been available to a
411 very broad audience, the firm should not make its detailed response with off-label information
412 publicly available within the same forum. For example, after the requestor has contacted the firm
413 and provided a personal e-mail address to obtain an answer to the off-label question, the firm’s

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414 detailed off-label response, within the parameters outlined in Section V of this draft guidance,
415 should be e-mailed to the requestor since this resulting communication will occur solely between
416 the firm and the specific individual making the unsolicited request for the off-label information.
417

418 3. Representatives who provide public responses to unsolicited requests for off-label information
419 should clearly disclose their involvement with a particular firm.
420

421 FDA recommends that a representative who responds to a public request clearly disclose in his/her
422 public response that he/she is a particular firm's representative and inform the requestor of the
423 name of the firm representative or department to contact should the individual choose to follow up
424 directly with the firm in a non-public forum for detailed information about the unsolicited request
425 for off-label information.
426

427 4. Public responses to public unsolicited requests for off-label information described in numbers
428 2 and 3 should not be promotional in nature or tone.
429

430 In addition to a firm's contact and disclosure information, a public response should include a
431 mechanism for providing readily accessible current FDA-required labeling, if any, for the product
432 (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient
433 labeling or, for new animal drugs, FDA-approved client information sheet). The public response
434 should *not* provide any promotional information. For example, a public online response should
435 include a direct link to the current FDA-required labeling, if any, but should *not* include links to
436 any other information (e.g., product websites, product promotional materials, firm websites, third-
437 party websites). Furthermore, the uniform resource locator (URL) or web address where viewers
438 are directed to obtain the FDA-required labeling, if any, should *not* itself be promotional in tone or
439 content (e.g., should not be www.bestcancercure.com).
440

441 If a firm responds to public unsolicited requests for off-label information, including those
442 encountered through emerging electronic media, in the manner described above, FDA does not
443 intend to use such responses as evidence of the firm's intent that its product be used for an
444 unapproved or uncleared use. Such responses also would not be expected to comply with the
445 disclosure requirements related to promotional labeling and advertising.