
Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs

Guidance for Industry

REVISED DRAFT GUIDANCE

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

**August 2015
Advertising
Revision 2**

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1 **Brief Summary and Adequate Directions for Use: Disclosing Risk**
2 **Information in Consumer-Directed Print Advertisements and**
3 **Promotional Labeling for Prescription Drugs**

4
5 **Guidance for Industry¹**
6

7
8 This revised draft guidance, when finalized, will represent the current thinking of the Food and Drug
9 Administration (FDA or Agency) on this topic. It does not create any rights for any person and is not
10 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
11 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
12 for this guidance as listed on the title page.
13

14
15
16 **I. INTRODUCTION**
17

18 This revised draft guidance provides recommendations on the disclosure of risk information in
19 prescription drug product advertisements and promotional labeling in print media directed
20 toward consumers with respect to the brief summary requirement and the requirement that
21 adequate directions for use be included with promotional labeling.² The recommendations
22 describe an alternative disclosure approach that FDA refers to as a *consumer brief summary*.
23 This revised draft guidance does not focus on the presentation of risk information in the main
24 body of promotional labeling or advertisements and does not apply to promotional materials
25 directed toward health care professionals.
26

27 This revised draft guidance responds to stakeholder requests for specific guidance on the
28 disclosure of risk information to consumers and incorporates recent social science research
29 results (Aikin, O'Donoghue, et al. 2011). This revised draft guidance revises the draft guidance
30 entitled *Brief Summary: Disclosing Risk Information in Consumer-Directed Print*
31 *Advertisements* (issued January 2004). Additionally, this revised draft guidance (Revision 2) has
32 been reissued to incorporate animal prescription drugs; there are no other revisions to the revised
33 draft guidance for industry issued February 9, 2015 (80 FR 6998).

¹ This guidance has been prepared by the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research (CBER) and the Center for Veterinary Medicine (CVM) at the Food and Drug Administration.

² The recommendations of this revised 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” 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, 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” in this guidance therefore also include biological products for use in humans that fall within the definition, as well as both human and animal prescription drugs.

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

39

40 **II. BACKGROUND**

41

42 **A. Legal Overview**

43

44 Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Agency has responsibility for
45 regulating the manufacture, sale, and distribution of drugs in the United States. This authority
46 includes oversight of the labeling of drugs (21 U.S.C. 352(a)) and the advertising of prescription
47 drugs (21 U.S.C. 352(n)).

48

49 A print advertisement³ for a prescription drug must contain a true statement of the product’s
50 established name; quantitative composition; information in brief summary relating to side
51 effects, contraindications, and effectiveness; and, for published direct-to-consumer
52 advertisements, a statement encouraging consumers to report negative side effects to FDA (21
53 U.S.C. 352(n)). FDA implementing regulations provide further clarification on the information
54 to include in brief summary: “a true statement of information in brief summary relating to side
55 effects, contraindications ([to] . . . include side effects, warnings, precautions, and
56 contraindications and include any such information under such headings as cautions, special
57 considerations, important notes, etc.) and effectiveness” (21 CFR 202.1(e)(1)). This information
58 “shall disclose each specific side effect and contraindication . . . contained in required, approved,
59 or permitted labeling for the advertised drug dosage form(s) . . .” (21 CFR 202.1(e)(3)(iii)). For
60 purposes of this guidance, the requirement under these provisions that an advertisement for a
61 prescription drug disclose each side effect, warning, precaution, and contraindication from the
62 labeling will be referred to as the *brief summary requirement*.

63

64 FDA also has responsibility for regulating labeling for prescription drugs, including promotional
65 labeling. Section 201(m) of the FD&C Act defines *labeling* as “all labels and other written,
66 printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2)
67 accompanying such article” (21 U.S.C. 321(m)).⁴ The U.S. Supreme Court has explained that
68 the language “accompanying such article” in the “labeling” definition is interpreted broadly, to
69 include materials that supplement or explain an article. No physical attachment between the
70 materials and the article is necessary; rather, it is the textual relationship between the items that
71 is significant (*Kordel v. United States*, 335 U.S. 345, 350 (1948)). FDA generally recognizes

³ The FD&C Act does not define what constitutes an “advertisement,” but FDA regulations provide several examples, including “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems” (21 CFR 202.1(l)(1)). Broadcast advertisements, such as radio and television advertisements, are not the subject of this guidance.

⁴ See also 21 CFR 1.3(a).

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72 two types of labeling for drugs: (1) FDA-required labeling⁵ and (2) promotional labeling.
73 Promotional labeling is generally any labeling, other than the FDA-required labeling, that is
74 devised for promotion of the product. Examples of materials that may be considered
75 promotional labeling pieces for prescription drugs are described in 21 CFR 202.1(l)(2).
76

77 While drug labeling generally must bear “adequate directions for use” (21 U.S.C. 352(f)(1),
78 prescription drugs are exempt from this requirement if certain conditions are met. These
79 conditions include, among others, that “any labeling” (as defined in section 201(m) of the FD&C
80 Act) that is “distributed by or on behalf of the manufacturer, packer, or distributor of the drug,
81 that furnishes or purports to furnish information for use or which prescribes, recommends, or
82 suggests a dosage for the use of the drug” contains “adequate information for such use” (21 CFR
83 201.100(d) and 21 CFR 201.105(d)). “Adequate information for such use” includes, among
84 other things, “relevant warnings, hazards, contraindications, side effects, and precautions, under
85 which practitioners licensed by law to administer the drug can use the drug safely and for the
86 purposes for which it is intended, including all conditions for which it is advertised or
87 represented . . .” (21 CFR 201.100(d)(1); see also 21 CFR 201.105(d)(1)).⁶ The regulations also
88 require that if the article is subject to section 505, 512, or 572 of the FD&C Act, the parts of the
89 labeling providing such information for use are the same “in language and emphasis” as labeling
90 approved or permitted under the provisions of sections 505, 512, or 572. (Id.)
91

92 In addition, in order to be exempt from the “adequate directions for use” requirement in 21
93 U.S.C. 352(f), any labeling for human prescription drugs described in 21 CFR 201.100(d) must
94 contain the “information required, and in the same format specified by” 21 CFR 201.56, 201.57,
95 and 201.80 (21 CFR 201.100(d)(3)). Generally, the requirements in 21 CFR 201.100(d) have
96 been fulfilled by including the full FDA-approved package insert (PI) with promotional labeling
97 materials. For purposes of this guidance, the requirement under these provisions that a
98 prescription drug promotional labeling piece include the information set forth in 21 CFR
99 201.100(d) for prescription human drugs and 21 CFR 201.105(d) for prescription animal drugs,
100 which is generally fulfilled by inclusion of the full PI, will be referred to as the *adequate*
101 *directions for use requirement*.
102

103 To fulfill the brief summary requirement, consumer-directed print advertisements for
104 prescription drugs frequently include the complete risk-related sections of the PI (also known as
105 the “traditional approach” or “traditional format”). To fulfill the adequate directions for use
106 requirement for promotional labeling pieces, the full PI has generally been used. As discussed
107 more fully in section II.B, FDA believes these approaches are not optimal for consumer-directed
108 prescription drug print advertisements and promotional labeling pieces because many consumers

⁵ 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), and 601.2(a)). For a prescription drug 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), and 201.105(c)(1)).

⁶ “Adequate information for use” under 21 CFR 201.100(d)(1) and 201.105(d)(1) also includes indications, effects, dosages, routes, methods, and frequency and duration of administration.

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109 lack the technical background to understand some of the information as described in the PI.
110 Additionally, information that may be of limited use to consumers (e.g., clinical pharmacology)
111 is included. For these reasons, if manufacturers, packers, and distributors, or anyone acting on
112 their behalf (firms) include the appropriate information discussed in this guidance, FDA does not
113 intend to object for failure to include each side effect from the PI in the brief summary in
114 consumer-directed print advertisements. Furthermore, if firms include the appropriate
115 information discussed in this guidance, FDA does not intend to object for failure to include the
116 entire PI to fulfill the requirements of 201.100(d) or 201.105(d) for consumer-directed
117 promotional labeling pieces.

118
119 In other words, this revised draft guidance recommends alternative approaches firms may use to
120 develop content that can be used to fulfill both the brief summary requirement for consumer-
121 directed prescription drug print advertisements and the requirements in 201.100(d) or 201.105(d)
122 for consumer-directed prescription drug print promotional labeling pieces. Suggested research-
123 tested formats for this information are also provided in this revised draft guidance. The
124 examples included throughout are intended to provide guidance and illustrate possible
125 approaches; firms may use alternative approaches if these approaches satisfy the requirements of
126 the statute and regulations.

127

B. Policy Overview

128

129
130 To provide better and more actionable information for consumers, FDA believes that the brief
131 summary should focus on the most important risk information rather than an exhaustive list of
132 risks and that the information should be presented in a way most likely to be understood by
133 consumers. Thus, FDA strongly recommends against the use of the traditional approach to fulfill
134 the brief summary requirement in consumer-directed advertisements, an approach in which risk-
135 related sections of the PI are presented verbatim, often in small font. Because the target audience
136 of the PI is health care providers, it is written in highly technical medical terminology, which is
137 potentially of limited value to consumers who may not have the medical or scientific background
138 to understand this information. In an FDA survey, few respondents reported reading half or
139 more of the brief summary presented in the traditional format. Of those who read at least some
140 of the brief summary, 55 percent described it as hard to read. Over 40 percent of respondents in
141 the survey reported they do not usually read any of the brief summary in direct-to-consumer
142 prescription drug print advertisements (Aikin, Swasy, et al. 2004).

143

144 Furthermore, the risk information in the PI sometimes includes lengthy lists of all possible
145 adverse events. In general, FDA believes that exhaustive lists that include even minor risks
146 detract from, and make it difficult for, consumers to comprehend and retain information about
147 the more important risks. While remaining an important source of information for consumers,
148 even the volume of material in excerpted sections of the PI, along with the format (i.e., a smaller
149 font with limited white space) and the technical language, may serve to detract from consumers'
150 comprehension of the information or from the likelihood of consumers reading the material in its
151 entirety. Research has demonstrated that people process only a limited amount of information at
152 one time both in general communications (Lavie 2001; Miller 1994; Shapiro 2001) and in direct-
153 to-consumer prescription drug advertising specifically (Stotka, Rotelli, et al. 2007). Past
154 research has shown that alternative formats for the brief summary outperform the traditional,

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155 non-consumer-friendly brief summary on measures of consumer risk comprehension (Riggs,
156 Holdsworth, et al. 2004; Schwartz, Woloshin, et al. 2009; Stotka, Rotelli, et al. 2007; Thumma
157 1997).

158
159 Occasionally, sections taken from the PI to fulfill the brief summary requirement are rewritten in
160 a manner that is meant to be more understandable to consumers. However, this approach does
161 not necessarily solve the problems with the traditional approach. In research conducted by FDA,
162 participants who viewed the brief summary information in a format similar to the over-the-
163 counter (OTC) “Drug Facts” box had better risk recall than those who viewed a traditional, but
164 consumer-friendly, version of the brief summary. Two additional alternative formats (a Question
165 and Answer (Q&A) format and a Highlights version from the content and format rule of 2006⁷)
166 did not differ from the consumer-friendly traditional format on risk recall or confidence (Aikin,
167 O’Donoghue, et al. 2011).⁸

168
169 For similar reasons that are further exacerbated by the length and complexity of the full approved
170 professional labeling, FDA also strongly recommends against providing the full PI to satisfy the
171 adequate directions for use requirement for consumer-directed print promotional labeling pieces
172 for prescription drugs. While the Agency recognizes that 21 CFR 201.100(d) and 21 CFR
173 201.105(d) identify the PI as a source for furnishing adequate directions for use, FDA believes
174 that following the content and format recommendations in this guidance will better communicate
175 information and help consumers make informed decisions about the medication being promoted.
176 By adopting the content and format recommendations in this guidance, firms can also provide
177 consumers with the same information in both advertising and promotional labeling pieces.

178 179 **III. OPTIONS FOR DISCLOSING RISK INFORMATION IN CONSUMER- 180 DIRECTED PRESCRIPTION DRUG PRINT ADVERTISEMENTS AND 181 PROMOTIONAL LABELING**

182
183 FDA does not intend to object if a firm does not include “each specific side effect and
184 contraindication” from the PI in the brief summary in consumer-directed print advertisements
185 (21 CFR 202.1(e)(3)(iii)), or does not supply the entire PI to fulfill the requirements in 21 CFR
186 201.100(d) or 21 CFR 201.105(d) for consumer-directed print promotional labeling pieces, so
187 long as the firm follows the recommendations and examples in this guidance. These alternate
188 approaches will not become a part of FDA-approved labeling.

189
190 **For purposes of this guidance, in the text and examples below, the consumer-directed**
191 **document recommended by FDA as an alternative to the full PI or the risk portions of the**
192 **PI in consumer-directed prescription drug print promotional labeling pieces and the brief**

⁷ See 21 CFR 201.56, 201.57, 201.58, and 201.80.

⁸ Participants who viewed the brief summary information in a format similar to the OTC Drug Facts box had better risk recall, greater confidence in their ability to perform tasks related to the brief summary, more positive attitudes toward the ad, and greater preference for the format than did those who viewed a traditional, but consumer-friendly, version of the brief summary. Participants had more positive attitudes toward the Q&A format and the Highlights format than toward the traditional format, and participants who viewed the Q&A format had more positive attitudes toward the ad than those who viewed the traditional format.

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193 **summary requirement in consumer-directed prescription drug advertisements will be**
194 **referred to as the “consumer brief summary.”**

195

196 **A. Language and Readability**

197

198 FDA strongly encourages the use of consumer-friendly language in all consumer-directed
199 materials. The consumer brief summary should be written in language designed for
200 understanding by a broad target audience with various levels of literacy skills. Technical
201 language, scientific terms, and medical jargon should be avoided. A conversational tone or
202 language designed to engage the reader may be useful, such as in the following examples.

203

- 204 • “do not use if you have . . .” or “who should not use . . .” rather than
205 “contraindications”
- 206 • “what is [drug name]” rather than “indication”
- 207 • “drowsiness” not “somnolence”
- 208 • “fainting” not “syncope”

209

210 The information in the consumer brief summary must be presented in a readable format (21
211 U.S.C. 352(c); 21 CFR 202.1(e)(7)(viii)). Different techniques can be used to assist consumers
212 with comprehension of information. For example, *signals*,⁹ such as headlines and subheadings,
213 help communicate important information (Loman and Mayer 1983; Meyer 2003; Spyridakis and
214 Standal 1987). Consumers are influenced by the layout of print information in their ability to
215 pay attention to and process specific features of a document (Adams and Edworthy 1995;
216 Brundage, Feldman-Stewart, et al. 2005; Frantz 1993; Morrow, Leirer, et al. 1995; Niemela and
217 Saariluoma 2003; Wogalter and Vigilante 2003). Font size and type style can affect the
218 readability of information (Adams and Edworthy 1995; Arditi and Cho 2005; Baker 2006;
219 Sheedy, Subbaram, et al. 2005; Tantillo and Mathisen 1995; Wogalter and Vigilante 2003).

220

221 Therefore, the consumer brief summary should be presented visually in a manner designed for
222 ease of use by consumers. Carrying over elements of the main body of the ad (such as logos and
223 branded colors) may help the reader understand the connection between the consumer brief
224 summary and the promotional piece. Font size and style should be selected or designed for
225 readability. Using double spacing between paragraphs and indentations, as opposed to plain
226 block paragraphs, helps maximize background space (also called *white space*) and improves
227 readability. Arranging information in text boxes (i.e., paragraphs of information on a similar
228 topic surrounded by borders) with headings (Hyona and Lorch 2004) and other attention-drawing
229 symbols (e.g., bullets, capitalization of select words or phrases) may also be useful to consumers.

230

231 **B. Content**

232

233 FDA’s current thinking is that the consumer brief summary should provide clinically significant
234 information on the most serious and the most common risks associated with the product and omit

⁹ “Signaling” has been defined as the use of “writing devices designed to emphasize aspects of a text’s structure or content without altering the information in the text” (Lorch, Lorch, et al. 1993).

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235 less pertinent information. FDA recommends that firms look to available standards to determine
236 which risks should be included. For example, FDA-approved patient labeling and Medication
237 Guides, or, for animal drugs, a client information sheet, if available for the drug at issue, may be
238 an appropriate starting point to determine which risks should be included in the consumer brief
239 summary and, in fact, may contain the same risk information that should appear in the consumer
240 brief summary. However, some information in patient labeling—such as information found in
241 the Directions for Use section (for human prescription drugs) or the client information sheet (for
242 animal drugs)—is not necessary to include in the consumer brief summary. Additionally,
243 information not contained in patient labeling, such as information about certain relevant drug
244 risks, might need to be added to the consumer brief summary.

245
246 Under the final rule for Requirements on the Content and Format of Labeling for Human
247 Prescription Drug and Biological Products (the “Physician Labeling Rule” or PLR),¹⁰ the
248 labeling of new and recently approved products¹¹ must include Highlights of Prescribing
249 Information (Highlights). FDA believes the criteria used for selecting risk information for the
250 Highlights section are an appropriate reference for firms to use when determining which risk
251 information topics to address in the consumer brief summary. See 21 CFR 201.57(a). In
252 addition, information in the consumer brief summary should be placed in an order similar to
253 information in the Highlights section (Boxed Warning followed by Contraindications, Warnings
254 and Precautions, etc.). However, since information in the Highlights section is intended for use
255 in conjunction with information in the full PI and the full PI is not being provided, generally the
256 information in the consumer brief summary should be more detailed and provide more material
257 information than what is contained in the Highlights. For drugs for which the PLR is not
258 applicable (i.e., new animal drugs and some human drugs), similar information can be taken
259 from the analogous sections of each drug’s PI.

260
261 For each of the formats discussed below, or for alternative formats, information addressing the
262 following should be included:

- 263
- 264 • Boxed Warning¹²
 - 265 • All Contraindications
 - 266 • Certain information regarding Warnings and Precautions:
 - 267 ○ the most clinically significant information from the Warnings and Precautions
 - 268 section(s) of the PI;
 - 269 ○ information that would affect a decision to prescribe or take a drug;
 - 270 ○ monitoring or laboratory tests that may be needed;
 - 271 ○ special precautions not set forth in other parts of the PI; and
 - 272 ○ measures that can be taken to prevent or mitigate harm.
- 273

¹⁰ Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products (71 FR 3922, Jan 24, 2006).

¹¹ The PLR applies to human prescription drugs that were approved after, on, or 5 years prior to the effective date of the rule, and to older drugs for which certain supplements are submitted (21 CFR 201.56(b)).

¹² Certain recommendations will not apply to all drugs. For example, not all drugs have a Boxed Warning. If a recommendation is not applicable, the information should be omitted.

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274 FDA also recommends that the most frequently¹³ occurring Adverse Reactions be included in the
275 consumer brief summary.¹⁴ If a product has more than one indication, the most common
276 Adverse Reactions for each indication being promoted should be included, if included in the PI,
277 rather than pooled results for all indications (which could include indications that are not being
278 promoted). Adverse Reactions should be listed in the same order as in the PI.

279

280 Other important Adverse Reactions, such as those that are serious¹⁵ or those that lead to
281 discontinuation of the drug or dosage adjustment, should be included unless they are repeated
282 elsewhere in the PI (e.g., risks included in Warnings and Precautions).

283

284 Material information regarding any of these risks may also include the severity of the risks, such
285 as whether they are debilitating, life-threatening, irreversible, or whether stopping the medication
286 will alleviate or mitigate the risks. If early warning signs of risks are known, consumers should
287 be given information about these signs and the importance of informing their health care
288 provider about the signs. Firms may also include information regarding the need for monitoring
289 or testing during treatment. Other material information may be relevant depending on the drug
290 and its risk profile.

291

292 FDA also believes that the consumer brief summary should include the indication for the use
293 being promoted, any clinically significant drug interactions,¹⁶ and information regarding topics
294 or issues consumers should discuss with their health care providers (e.g., other drugs they are
295 taking or pre-existing conditions). Other types of information may be included if relevant to the
296 drug or specific indication referred to in the promotion (e.g., that a drug is not indicated for use
297 for more than 4 weeks for the indication being advertised even if a different indication allows for
298 a longer use). Information relating to special populations (e.g., children or young animals, the
299 elderly or geriatric animals, pregnant or nursing women or animals, people or animals with liver
300 or renal impairment, food-producing animals) should be included if they are of particular

¹³ The list of Adverse Reactions identified as most frequently occurring or most common is usually generated from a table of Adverse Reactions from clinical trials in the approved labeling. Rates of most common Adverse Reactions vary, but should be appropriate to the nature of a drug's Adverse Reactions profile and the size and composition of the safety database. See the guidance for industry entitled *Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements* (Feb 2013), available on the Internet at <http://www.fda.gov/Drugs/default.htm> under Guidances (Drugs).

¹⁴ This recommendation comports with the information required in the Highlights section (21 CFR 201.57(a)(11)), and is also applicable to drugs to which the PLR does not apply.

¹⁵ *Serious Adverse Reaction* refers to any reaction occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious Adverse Reactions when, based upon appropriate medical judgment, they may jeopardize the patient or subject, and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. See the guidance for industry entitled *Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format* (Jan 2006). For animal drugs, the term “serious adverse drug experience” is defined as “an adverse event that is fatal, or life-threatening, or requires professional intervention, or causes an abortion, or stillbirth, or infertility, or congenital anomaly, or prolonged or permanent disability, or disfigurement” (21 CFR 514.3).

¹⁶ For example, for a drug with PLR labeling, typically the most clinically significant drug interactions appear in the Contraindications or Warnings and Precautions sections.

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301 concern based on the drug’s known or potential safety profile (e.g., not recommended for use in
302 children based on adverse events; not for use in nursing women due to the potential for harm to
303 the infant; drug withdrawal periods in different animal populations).
304

305 In general, certain information found in the PI or in FDA-approved patient labeling can be
306 excluded from the consumer brief summary. This information might include dosage and
307 administration, how the drug is supplied, clinical pharmacology, specific directions regarding use
308 of the drug (such as how to perform an injection or how to use a patch), or how long the drug
309 takes to work. However, excluding certain information from the consumer brief summary does
310 not mean that the same information can be omitted from other parts of the promotional piece
311 (e.g., information that a drug is administered via an injection versus orally might be material
312 information that is required in the main body of the promotional piece, while detailed
313 instructions for use may be omitted from the consumer brief summary).
314

315 FDA also recommends that, because the risk information in the consumer brief summary is not
316 comprehensive, the consumer brief summary should include a statement (1) reminding
317 consumers that the information presented is not comprehensive; (2) suggesting that consumers
318 speak to their health care provider, veterinarian, or pharmacist; and (3) containing a toll-free
319 telephone number or website address (uniform resource locator or URL) where consumers can
320 obtain the FDA-approved product labeling.¹⁷ For example:
321

- 322 • *The risk information provided here is not comprehensive. To learn more, talk*
323 *about [drug name] with your health care provider or pharmacist [veterinarian].*
324 *The FDA-approved product labeling can be found at www.drugnamePI.com or 1-*
325 *800-555-DRUG.*
- 326
- 327 • *This information is not comprehensive.*
- 328 • *How to get more information:*
 - 329 ▪ *Talk to your health care provider or pharmacist [veterinarian]*
 - 330 ▪ *Visit www.drugnamePI.com to obtain the FDA-approved product labeling*
 - 331 ▪ *Call 1-800-555-DRUG*
 - 332

333 The consumer brief summary may also contain a title such as “Important Facts” or “Summary of
334 Information about . . .” along with the drug’s name.¹⁸
335

336 When the PI is revised, the consumer brief summary for the drug must be reviewed and revised
337 promptly if pertinent information has been changed (21 CFR 314.70(a)(4), 514.8(c)(2), and
338 601.12(a)(4)).
339

¹⁷ This recommendation is distinct and separate from the “adequate provision” requirement for broadcast advertisements found at 21 CFR 202.1(e)(1). This guidance only covers print advertisements and print promotional labeling and does not apply to broadcast advertisements.

¹⁸ See the revised draft guidance for industry entitled *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling* (Nov 2013). When final, this guidance will represent the FDA’s current thinking on this topic.

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340 C. Format

341

342 Various formats may be used when conveying information in the consumer brief summary.
343 Although other formats may be acceptable, the following two sections describe recommended
344 formats that have been tested in research.

345

346 1. *Prescription Drug Facts Box*

347

348 Ever since the labeling rule for OTC human drugs was finalized more than a decade ago,¹⁹ OTC
349 products have contained a Drug Facts box on each product. For the consumer brief summary, a
350 layout similar to the OTC Drug Facts box may be familiar to consumers and may offer
351 advantages over other formats. In a study testing various brief summary formats, the Drug Facts
352 box format resulted in better recall of the risk information when compared to the traditional
353 format (which was written in consumer-friendly language). Consumers in the same study who
354 saw the Drug Facts box also reported that they felt more confident in their ability to use the
355 information when compared to consumers who saw the traditional format. In addition,
356 consumers had more positive attitudes toward the Drug Facts box format than toward two other
357 formats: the traditional format and a format that is structured like the Highlights section of the
358 PI (Aikin, O'Donoghue, et al. 2011).

359

360 Under a prescription Drug Facts box format, information could appear within a box similar to the
361 OTC Drug Facts box. Standardized headings may assist consumers in locating and
362 comprehending important drug information. For example:

363

- 364 • Uses
- 365 • Do not use if you
- 366 • Warnings
- 367 • Ask a health care provider before use if
- 368 • When using this product you may have

369

370 The recommended content for this format is set forth in section III.B above, and the
371 recommendation to use consumer-friendly language also applies.

372

373 2. *Question and Answer*

374

375 A Question and Answer (Q&A) format simulates a dialogue using personal pronouns, thus
376 increasing consumer interest in, and comprehension of, the information. The study testing brief
377 summary formats found that consumers had more positive attitudes toward a Q&A format than
378 the traditional brief summary (which was written in consumer-friendly language). However, this
379 study did not find a difference in risk recall or confidence between the Q&A format and the
380 traditional format. Because consumers preferred the Q&A format and the format did not

¹⁹ See Food and Drug Administration, “Final Rule; Over-The-Counter Human Drugs, Labeling Requirements” (64 FR 13254, Mar 17, 1999).

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381 decrease risk recall (Aikin, O'Donoghue, et al. 2011), this format is recommended over the
382 traditional brief summary.

383

384 Under the Q&A format, information in the consumer brief summary could appear in columns or
385 a similar layout. Headings would be framed in the form of questions, for example:

386

387

- What is [drug] used for?

388

- When should I not take [drug]?

389

- What Warnings should I know about [drug]?

390

- What should I tell my health care provider?

391

- What are the side effects of [drug]?

392

- What other medications might interact with [drug]?

393

394 The recommended content for this format is set forth in section III.B above, and the
395 recommendation to use consumer-friendly language also applies.

396

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