
Guidance for Industry

Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products — Content and Format

DRAFT GUIDANCE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)**

**September 2013
Labeling**

Guidance for Industry

Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products — Content and Format

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1 **Guidance for Industry¹**
2 **Patient Counseling Information Section of Labeling for Human**
3 **Prescription Drug and Biological Products — Content and Format²**
4

5
6 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current
7 thinking on this topic. It does not create or confer any rights for or on any person and does not operate to
8 bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of
9 the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA
10 staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call
11 the appropriate number listed on the title page of this guidance.
12

13
14 **I. INTRODUCTION**
15

16 This guidance is intended to assist applicants with developing the PATIENT COUNSELING
17 INFORMATION section of labeling required under § 201.57(c)(18) (21 CFR 201.57(c)(18)).
18 The recommendations in this guidance are intended to help ensure that this section of labeling is
19 clear, useful, informative, and to the extent possible, consistent in content and format.
20

21 This guidance is intended to assist applicants with the following:
22

- 23 • How to decide what topics to include in the PATIENT COUNSELING INFORMATION
24 section
- 25
- 26 • How to present information in the PATIENT COUNSELING INFORMATION section
27
- 28 • How to organize the PATIENT COUNSELING INFORMATION section
29

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

36 **II. BACKGROUND**
37

38 On January 24, 2006, FDA published a final rule that amended requirements for the content and
39 format of labeling for human prescription drug and biological products (commonly referred to as

¹ This guidance has been prepared by the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA or the Agency).

² This guidance applies to drugs, including biological products. For the purposes of this guidance, *drug product or drug* will be used to refer to human prescription drug and biological products that are regulated as drugs.

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40 the “Physician Labeling Rule” or “PLR”).³ The rule created a new required section in labeling
41 entitled PATIENT COUNSELING INFORMATION (§ 201.57(c)(18)). The PATIENT
42 COUNSELING INFORMATION section should summarize the information that a health care
43 provider should convey to a patient (or caregiver when applicable) when a counseling discussion
44 is taking place (e.g., a physician prescribing a drug during an office visit, a nurse providing
45 discharge instructions at a hospital, or a pharmacist conveying information at a pharmacy).
46 Under § 201.57(c)(18), the PATIENT COUNSELING INFORMATION section of labeling must
47 contain the following:

- 48
- 49 • Information necessary for patients to use the drug safely and effectively.
- 50
- 51 • If applicable, reference to FDA-approved patient labeling; the full text of such patient
52 labeling must be reprinted immediately following the full prescribing information (FPI)
53 or, alternatively, accompany the prescribing information.
- 54

55 Before FDA published the final rule, labeling regulations required that any information
56 necessary for patients to use the drug safely and effectively be presented under Information for
57 Patients, a subsection of the PRECAUTIONS section of labeling.⁴ By requiring a dedicated
58 section to such information in labeling in the PLR format, FDA underscored the importance of
59 health care providers’ counseling of patients. As labeling in the old format is converted to the
60 PLR format in accordance with the implementation schedule under 21 CFR 201.56(c), applicants
61 with labeling that did not include an Information for Patients subsection must develop a
62 PATIENT COUNSELING INFORMATION section unless the section is clearly inapplicable
63 and omitted under § 201.56(d)(4) (21 CFR 201.56(d)(4)) (see section III).

64

65 Because regulatory requirements for the PATIENT COUNSELING INFORMATION section are
66 broadly worded and many different presentations have been used in labeling approved in PLR
67 format, this guidance seeks to (1) provide recommendations on how to select information to
68 include and (2) bring greater consistency to the content and format of the PATIENT
69 COUNSELING INFORMATION section.

III. CONTENT

70

71

72

73 The PATIENT COUNSELING INFORMATION section is written for use by a health care
74 provider to identify topics for a counseling discussion. Therefore, the content and presentation
75 of information in the PATIENT COUNSELING INFORMATION section typically will differ
76 from those in FDA-approved patient labeling (e.g., Patient Package Inserts, Medication Guides,
77 and Instructions for Use). The PATIENT COUNSELING INFORMATION section should
78 contain the most important information for providers to convey to patients for the safe and
79 effective use of a drug. Consequently, all topics presented in the PATIENT COUNSELING

³ *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products* (January 24, 2006, 71 FR 3922)

The requirements are found at §§ 201.56 and 201.57.

⁴ Prescription drug products not described under § 201.56(b)(1) are not subject to § 201.57(c)(18), but are subject to 21 CFR 201.80(f)(2) addressing the Information for Patients subsection.

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80 INFORMATION section should typically be included in FDA-approved patient labeling.
81 Information in the PATIENT COUNSELING INFORMATION section and any FDA-approved
82 patient labeling, along with the provider-patient conversation, are essential and complementary
83 components for the safe and effective use of prescription drugs.
84

85 The PATIENT COUNSELING INFORMATION section is required in all labeling subject to
86 § 201.57, including for drugs used in an inpatient setting or other health care settings, such as a
87 clinic or physician’s office. In extremely rare circumstances, the section may be omitted if its
88 inclusion would be clearly inapplicable (e.g., labeling for standard intravenous fluids) as allowed
89 under § 201.56(d)(4).
90

91 Requirements and recommendations for the content of the PATIENT COUNSELING
92 INFORMATION section are presented in section III.A through C.
93

A. Reference to FDA-Approved Patient Labeling

94
95 Under § 201.57(c)(18), if a product has FDA-approved patient labeling (e.g., Patient Package
96 Insert, Medication Guide, and Instructions for Use), such labeling must be referenced in the
97 PATIENT COUNSELING INFORMATION section. The reference to patient labeling informs
98 health care providers of the existence of approved patient labeling and should direct them to
99 advise patients to read such labeling.
100

101 The reference statement should appear first in the PATIENT COUNSELING INFORMATION
102 section and identify the type(s) of FDA-approved patient labeling. Recommended options for
103 the reference statement include:
104

- 105
- 106 • Advise the patient to read the FDA-approved patient labeling (Patient Information).⁵
- 107
- 108 • Advise the patient to read the FDA-approved patient labeling (Instructions for Use).
- 109
- 110 • Advise the patient to read the FDA-approved patient labeling (Patient Information and
- 111 Instructions for Use).
- 112
- 113 • Advise the patient to read the FDA-approved patient labeling (Medication Guide).
- 114
- 115 • Advise the patient to read the FDA-approved patient labeling (Medication Guide and
- 116 Instructions for Use).
- 117

118 If counseling for a particular product is typically directed to a caregiver rather than the patient,
119 the statements can be modified accordingly.
120

B. Counseling Topics

⁵ In this reference statement, “Patient Information” is used instead of “Patient Package Insert” because “Patient Information” more clearly identifies the purpose of and audience for the information and is generally used as the title of the FDA-approved patient labeling that is appended to the end of the FPI.

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123 Information in the PATIENT COUNSELING INFORMATION section typically focuses on
124 major risks of the drug and, when appropriate, how the patient may mitigate or manage them.
125 This section should also include, when appropriate, other information relevant for providers to
126 convey to patients, such as critical administration instructions or unique storage and handling
127 instructions. In addition, there may be other information that is important for the health care
128 provider to convey to the patient, such as a common drug effect that does not pose a risk to
129 patients but could be important because it may be worrisome or potentially affect compliance
130 (e.g., cough from the use of angiotensin-converting enzyme inhibitors).

131
132 Not every risk discussed in labeling will always be included in the PATIENT COUNSELING
133 INFORMATION section. Only those topics critical for safe and effective use of the drug and
134 appropriate for a provider-patient discussion should be included. These would typically include
135 the most important risks about which patients should be informed and those for which a patient
136 may need to do something actionable (e.g., contact the prescriber, immediately discontinue the
137 drug, or seek emergency medical care). Topics presented elsewhere in labeling that provide
138 information relevant only for the prescriber or other health care provider should typically not
139 appear in the PATIENT COUNSELING INFORMATION section. Examples include
140 information pertinent to proper patient selection, an explanation of the interpretation of
141 laboratory results, or issues related to proper drug administration in an inpatient setting.

1. Presentation of the Information

142
143
144
145 The PATIENT COUNSELING INFORMATION section should summarize each topic to
146 facilitate discussion between a health care provider and a patient and should include the level of
147 detail appropriate for a counseling discussion. This focus and level of detail is typically not the
148 same as the discussion of the related topic or risk described elsewhere in the FPI. The
149 information in the PATIENT COUNSELING INFORMATION section should not be presented
150 simply as a list of risks from use of the drug, nor should the information be a repeat of entire
151 paragraphs from elsewhere in the labeling. Only in very rare instances will an entirely new
152 concept be included in the PATIENT COUNSELING INFORMATION section that does not
153 have a related discussion elsewhere in labeling.

154
155 Consistent with the approach used for other sections of labeling (e.g., BOXED WARNING,
156 WARNINGS AND PRECAUTIONS), information in the PATIENT COUNSELING
157 INFORMATION section should be ordered by the relative clinical significance of the
158 information, with the most important topics applicable to the patient appearing first. For this
159 reason the topics presented may or may not reflect the order in which they first appear overall in
160 the FPI (i.e., within the PATIENT COUNSELING INFORMATION section, a topic from the
161 WARNINGS AND PRECAUTIONS section may appear before a topic from the DOSAGE
162 AND ADMINISTRATION section).

163
164 Information in the PATIENT COUNSELING INFORMATION section should typically be
165 presented using active voice (e.g., “Advise the patient to...”), rather than passive voice (e.g.,
166 “Patients should be advised to...”), to provide clearer directives to the reader.

167

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2. *Types of Information to Consider for Inclusion*

a. Important adverse reactions and other risks

The PATIENT COUNSELING INFORMATION section summarizes important adverse reactions and other risks to convey to patients. Information should typically include, as appropriate, the identification of the risk, management recommendations that are pertinent to patients, self-monitoring information, and information on when to contact a health care provider, seek emergency help, or discontinue the drug. For example:

Serious Allergic Reactions

Advise the patient to discontinue DRUG-X and seek immediate medical attention if any signs or symptoms of a hypersensitivity reaction occur [*see Warnings and Precautions (5.X)*].

A listing of the most common adverse reactions should not be included in the PATIENT COUNSELING INFORMATION section. However, an individual common adverse reaction should be included if it is among the most important adverse reactions (e.g., appears in WARNINGS AND PRECAUTIONS) or the risk of its occurrence is important to convey to a patient (e.g., urine discoloration from use of rifampin).

b. Contraindications

Although contraindications are essential for informing prescribing decisions, they are typically not appropriate for a patient counseling discussion that occurs once a prescribing decision has been made. Some contraindications, however, may warrant inclusion in this the PATIENT COUNSELING INFORMATION section for conditions that may develop after starting drug therapy (e.g., development of an acute infection).

c. Drug interactions

Interactions or effects from other drugs or foods should be included in the PATIENT COUNSELING INFORMATION section if they concern an important risk (e.g., are mentioned in the BOXED WARNING, CONTRAINDICATIONS, or WARNINGS AND PRECAUTIONS section). Additionally, an interaction should be included if coadministration could be initiated by the patient (e.g., an interaction with food or an over-the-counter drug or dietary supplement). A complete listing of known drug interactions should typically not be included in the PATIENT COUNSELING INFORMATION section because the decision to coadminister two drugs generally rests with the provider at the time of prescribing.

In rare cases, a drug may have multiple serious drug interactions (e.g., warfarin or certain antiretroviral drugs) that would warrant a broadly worded recommendation in the PATIENT COUNSELING INFORMATION section to inform patients of the overall risk. A cross-reference would direct the health care provider to the more detailed discussion elsewhere in labeling.

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214 d. Information on use in pregnancy and lactation

215
216 Consistent with the approach taken for drug interactions, a discussion of the risks of a drug in
217 pregnancy or during lactation should be included in the PATIENT COUNSELING
218 INFORMATION section if the information concerns an important risk (e.g., is mentioned in the
219 BOXED WARNING, CONTRAINDICATIONS, or WARNINGS AND PRECAUTIONS
220 section). If the drug has no such risk, general advice on the use of drugs during pregnancy or
221 lactation (e.g., “Advise a female patient to inform the prescriber if she is pregnant or planning to
222 become pregnant”) should not be included in the PATIENT COUNSELING INFORMATION
223 section (see Section III.C. Information Not to Include).

224
225 Additionally, if there is a pregnancy exposure registry mentioned in the Pregnancy subsection of
226 the USE IN SPECIFIC POPULATIONS section, the availability of the registry should be
227 included in the PATIENT COUNSELING INFORMATION section, with a cross-reference to
228 the Pregnancy subsection where the contact information necessary to enroll may be found.

229
230 e. Information on preparation and administration

231
232 Full details on proper preparation and administration of a drug should typically appear in the
233 DOSAGE AND ADMINISTRATION section, while the PATIENT COUNSELING
234 INFORMATION section should summarize the most important points relevant to a counseling
235 conversation. For example:

236
237 Importance of Second Application

238 Inform the patient that the second application of DRUG-X is necessary to kill any
239 live lice that hatch following the initial treatment [*see Dosage and Administration*
240 (2.X)].

241
242 In general, the PATIENT COUNSELING INFORMATION section should not include typical
243 dosage regimen information (e.g., instructions to take one 30 mg tablet every 12 hours) for drugs
244 that are self-administered by the patient. However, pertinent advice on how to self-administer
245 should be briefly summarized if there are specific instructions for administration that need to be
246 followed so that the drug is used safely and effectively. Specific information may include, for
247 example, instructions to take the drug with a high-fat meal or an atypical dosing schedule (e.g.,
248 tapered dosing of prednisone). For example:

249
250 Administration Instructions

251 Advise the patient to swallow DRUG-X capsules intact and not to open, chew, or
252 crush the capsules. Inform the patient that the nonabsorbable DRUG-X capsule
253 shell may be visible in the stool.

254
255 If a product has FDA-approved patient labeling that includes details on self-administration (e.g.,
256 Instructions for Use), the detailed information should not be repeated verbatim in the PATIENT
257 COUNSELING INFORMATION section. The reference statement appearing at the beginning
258 of the PATIENT COUNSELING INFORMATION section directs health care providers to
259 advise patients to read FDA-approved patient labeling.

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260
261 For self-administered injectable drugs, information regarding proper sharps disposal will
262 typically be included in the FDA-approved Instructions for Use. The PATIENT COUNSELING
263 INFORMATION section should include a statement directing providers to advise patients to
264 follow sharps disposal recommendations,⁶ but should not summarize or repeat the information
265 found in the Instructions for Use.

- 266
267 f. Products with restricted distribution as a component of a Risk Evaluation
268 and Mitigation Strategies (REMS) program

269
270 Reference to the existence of a REMS program that includes restricted distribution should be
271 included in the PATIENT COUNSELING INFORMATION section along with a brief
272 description of only those program elements that directly impact the patient (e.g., a requirement to
273 enroll in the program, the availability of the drug only from pharmacies participating in the
274 program). If no elements of restricted distribution directly impact patients, information
275 regarding the REMS program should not appear in the PATIENT COUNSELING
276 INFORMATION section.

- 277
278 g. Instructions related to storage and handling

279
280 In rare cases, there may be important, atypical storage or handling information appropriate for a
281 provider-patient discussion that should be included in the PATIENT COUNSELING
282 INFORMATION section. For example:

283
284 Handling Instructions

285 Advise the patient that females of reproductive potential should not handle broken
286 or crushed DRUG-X tablets because DRUG-X may cause harm to a male fetus
287 [*see Warnings and Precautions (5.X)*].
288

289 As with preparation and administration instructions, the same topics may be discussed among the
290 PATIENT COUNSELING INFORMATION section, the HOW SUPPLIED/STORAGE AND
291 HANDLING section, and FDA-approved patient labeling regarding proper storage and handling,
292 but the focus of the discussion should reflect the intent of the section of labeling in which the
293 information resides.

- 294
295 h. Additional requirements

296
297 Certain products have additional, specific requirements for the PATIENT COUNSELING
298 INFORMATION section based on the product's therapeutic or pharmacologic class (e.g., 21
299 CFR 201.24(d) for systemic antibacterial drug products).
300

⁶ Information about safe disposal of needles and other sharps outside of health care settings is available on the Internet at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm>.

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301 **C. Information Not to Include**

302
303 The PATIENT COUNSELING INFORMATION section is intended to facilitate the provider-
304 patient discussion, but is not intended to serve as a script for the provider. For this reason not all
305 information related to use of a drug should be included in the PATIENT COUNSELING
306 INFORMATION section.

307
308 Examples of information that should generally not be included in the PATIENT
309 COUNSELING INFORMATION section include:

- 310 • Indication or use of a drug
- 311
- 312
- 313 • General recommendations lacking context that would be considered a standard
314 component of any provider-patient discussion (e.g., “Discuss the risks and benefits of
315 DRUG-X”)
- 316
- 317 • General advice that could apply to any drug (e.g., “Instruct the patient to keep
318 DRUG-X out of reach of children”) unless particularly relevant for an individual
319 product (e.g., the need to keep opioid-containing patches away from children and
320 pets)
- 321
- 322 • Information that informs prescribing decisions (e.g., “DRUG-X is contraindicated in
323 patients with a history of thromboembolic events”)
- 324
- 325 • Routine storage or handling information that would typically be conveyed to the
326 patient at the time of dispensing (e.g., the need to store an oral solution in the
327 refrigerator at home)
- 328
- 329 • Definitions or descriptions of medical terminology (e.g., a listing of signs and
330 symptoms of neuroleptic malignant syndrome, a potential serious adverse reaction
331 from the use of antipsychotic drugs) that need not be explained to a health care
332 provider audience
- 333
- 334 • Graphics (e.g., illustrations or pictures related to administration)
- 335

336 **IV. FORMAT**

337
338 The PATIENT COUNSELING INFORMATION section is subject to the applicable formatting
339 requirements under §§ 201.56(d) and 201.57(d). Additional recommendations are presented in
340 sections IV.A through C.

341 **A. Subheadings**

342
343
344 Following the required reference to any FDA-approved patient labeling, information in the
345 PATIENT COUNSELING INFORMATION section should be presented in a consistent format
346 that enhances its readability and usefulness. The use of subheadings to organize and differentiate

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347 topics within the PATIENT COUNSELING INFORMATION section is recommended because
348 they allow the reader to quickly identify the major concepts. Subheading titles should clearly
349 identify the focus of each discussion (e.g., Acute Hepatic Failure rather than simply Hepatic).

350
351 Because the content presented about each topic is generally one or two short statements,
352 numbered subsections (e.g., 17.1, 17.2) are typically unnecessary and are not recommended.
353 Moreover, numbered subsections cause unnecessary length and clutter in both the PATIENT
354 COUNSELING INFORMATION and in Contents (§ 201.57(b)) and may be redundant with
355 subsection titles elsewhere in the labeling (e.g., the WARNINGS AND PRECAUTIONS
356 section).

B. Cross-Referencing

357
358
359
360 Because information under the PATIENT COUNSELING INFORMATION section typically
361 summarizes information presented elsewhere in the labeling, cross-referencing should be used to
362 direct the reader to the more detailed discussion. If, however, the other section of the labeling
363 where the related topic is discussed contains no more information than appears in the PATIENT
364 COUNSELING INFORMATION section, no cross-reference is necessary.

C. Appending FDA-Approved Patient Labeling

365
366
367
368 If FDA-approved patient labeling immediately follows the FPI, the FDA-approved patient
369 labeling should not be assigned a subsection number and should instead be separated from the
370 FPI by other formatting techniques (e.g., a horizontal line or page break).