
Guidance

Useful Written Consumer Medication Information (CMI)

DRAFT GUIDANCE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)**

**May 2005
Procedural**

Guidance

Useful Written Consumer Medication Information (CMI)

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Guidance on Useful Written Consumer Medication Information (CMI)¹

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can 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 page of this guidance.

I. INTRODUCTION

This guidance is intended to assist individuals or organizations (e.g., pharmacies, private vendors, healthcare associations) in developing useful written consumer medication information (CMI). CMI is written information about prescription drugs developed by organizations or individuals other than a drug's manufacturer that is intended for distribution to consumers at the time of drug dispensing. Since neither FDA nor a drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the guidance contained in this document to ensure that their CMI is useful to consumers.

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

II. BACKGROUND

Traditionally, FDA has believed that people are able to make better decisions about their healthcare and better use of the prescription medications available to them when they are well informed about the medications they take. Access to useful written information about prescription medications is important to ensuring appropriate use of these products. Over the years, FDA has undertaken a number of efforts to help ensure that consumers receive useful, reader-friendly written information regarding their prescription medications. These efforts are described briefly here.

¹ This guidance has been prepared by the Office of Drug Safety in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

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43 Since 1968, FDA regulations have required that patient package inserts, written specifically for
44 patients, be distributed to patients when certain prescription drugs, or classes of prescription
45 drugs, are dispensed (see 21 CFR 310.501 for oral contraceptives and 310.515 for estrogens). In
46 the 1970s, however, FDA began evaluating the general usefulness of patient labeling for
47 prescription drugs, resulting in a series of regulatory steps to help ensure the availability of
48 useful written consumer information:

- 49
- 50 • In 1979, FDA proposed regulations that would require written patient information for all
51 prescription drugs (44 FR 40016; July 6, 1979).
 - 52 • In 1980, FDA finalized those regulations. They established requirements and procedures
53 for the preparation and distribution of manufacturer-prepared and FDA-approved patient
54 labeling for a limited number of prescription drugs (45 FR 60754; September 12, 1980).
 - 55 • In 1982, FDA revoked those regulations, in part based on assurances by pharmaceutical
56 manufacturers, healthcare professional associations, and private-sector providers of
57 written medication information for patients that the goals of the final rule would be met
58 more effectively and with greater innovation without regulation (47 FR 39147,
59 September 7, 1982).

60 FDA committed to monitor the progress of this private-sector effort. Unfortunately, periodic
61 FDA surveys showed that, although the distribution of written prescription drug information
62 increased, the usefulness of the information was highly variable. As a result:

- 63 • In 1995, FDA proposed a regulation entitled *Prescription Drug Product Labeling:
64 Medication Guide Requirements* (60 FR 44182; August 24, 1995), designed to set
65 specific distribution and quality goals and time frames for distributing written
66 information.

67 The regulation had the following goals:

- 68 – By the year 2000, 75 percent of people receiving new prescriptions would receive
69 useful written patient information with their prescriptions.
- 70
- 71 – By 2006, 95 percent of people receiving new prescriptions would receive useful
72 written patient information with their prescriptions.
- 73

74 The proposed rule would also require manufacturers to prepare and distribute Medication Guides
75 for a limited number of prescription drug products that posed a serious and significant public
76 health concern. In addition, the proposed rule described criteria for *usefulness* to permit
77 evaluation of whether the information met the target goals.²
78

² FDA also specified that the usefulness of written patient information would be evaluated based on scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

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- 79 • On August 6, 1996, as FDA was reviewing the public comments on the 1995 proposed
80 rule, Public Law 104-180 was enacted.³

81
82 This law adopted goals and time frames consistent with the 1995 proposed rule. The
83 legislation also established a voluntary private-sector process through which a committee of
84 interested stakeholders would develop a long-range comprehensive action plan to achieve the
85 goals specified in the statute. The law prohibited FDA from taking further regulatory steps
86 specifying a uniform content or format for written information voluntarily provided to
87 consumers about prescription drugs if private-sector initiatives met the goals of the plan
88 within the specified time frames.

- 89
90 • In 1996, a Steering Committee was created.

91 The Steering Committee, consisting of healthcare professionals, consumer organizations,
92 voluntary health agencies, pharmaceutical manufacturers, prescription drug wholesalers, drug
93 information database companies, CMI developers, and others, developed a report entitled
94 *Action Plan for the Provision of Useful Prescription Medicine Information* (the Action
95 Plan).⁴ The Action Plan delineated *criteria* for evaluating whether a particular piece of
96 written medication information is useful to consumers. The Action Plan endorsed the
97 elements specified in Public Law 104-180 for defining the usefulness of medication
98 information. Specifically, the Action Plan stated materials should be:

- 99 – scientifically accurate
100 – unbiased in content and tone
101 – sufficiently specific and comprehensive
102 – presented in an understandable and legible format that is readily comprehensible to
103 consumers
104 – timely and up-to-date
105 – useful, that is, enables the consumer to use the medicine properly and appropriately,
106 receive the maximum benefit, and avoid harm

- 107 • In 1998, FDA contracted with the National Association of Boards of Pharmacy (NABP)
108 to conduct CMI assessment.

109
110 The NABP performed a pilot study to test the usefulness of the CMI being developed. The
111 NABP also conducted a national study to assess the extent to which the year 2000 goals

³ Public Law 104-180, Title VI, Sec 601 Effective Medication Guides, 110 Stat 1593 (1996).

⁴ Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, unpublished report submitted to The Honorable Donna E. Shalala, Secretary of the U. S. Department of Health and Human Services, December 1996, available on the Internet at <http://www.fda.gov/cder/offices/ods/keystone.pdf>. Secretary Shalala accepted the Action Plan by letter dated January 13, 1997.

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112 specified in the law had been achieved. The results of the study were announced in 2002.
113 On average, 89 percent of the patients in the study received some form of written medication
114 information. However, the average *usefulness* of the information was only about 50 percent.⁵
115

- 116 • On July 17, 2002, the FDA Drug Safety and Risk Management Advisory Committee
117 (Advisory Committee) met to review the study results and public comments.
118

119 The Advisory Committee recommended that FDA take a more active role in advising and
120 encouraging the private sector to meet the next target goal set for year 2006.⁶
121

122 In response to that recommendation, the agency met with various groups, held a public meeting
123 in 2003 (see www.fda.gov/cder/offices/ods/writtenPrescripinfo.htm), and was asked to provide
124 clarification on how the Action Plan should be interpreted and implemented. This guidance is
125 part of FDA's efforts to assist developers of CMI. This guidance provides recommendations to
126 developers of CMI regarding how best to evaluate current CMI and develop future CMI to
127 ensure that all CMI meets the usefulness criteria provided in the Action Plan. FDA views the
128 *criteria* and *components* described in the Action Plan as the minimum appropriate characteristics
129 of *useful* CMI. Throughout this guidance, in explaining its views about the Action Plan criteria,
130 FDA uses the wording of the Action Plan as much as possible.
131
132

133 **III. APPLYING THE ACTION PLAN CRITERIA FOR CMI**

134 **A. General Considerations**

135
136
137 As discussed above, by 2006, 95 percent of people who receive new prescriptions should receive
138 useful written patient information with their prescriptions. To determine whether CMI
139 developers have met that goal, FDA will evaluate CMI against the Action Plan's criteria for
140 usefulness. This guidance is intended to assist developers of CMI in meeting the 2006 goal by
141 providing specific recommendations regarding the minimum appropriate characteristics of useful
142 CMI.
143

144 CMI that adheres to the Action Plan criteria for a specific prescription drug will be considered
145 *useful* when (1) the most recent FDA-approved professional labeling or package insert (PI) (see
146 21 CFR 201.56 and 201.57) serves as the source document for the information contained in

⁵ Svarstad, B.L. and J.K. Mount, *Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001*, final report to the U.S. Department of Health and Human Services and the Food and Drug Administration, December 2001, available on the Internet at <http://www.fda.gov/cder/reports/prescriptioninfo/default.htm>.

⁶ A transcript of FDA's Drug Safety and Risk Management Advisory Committee meeting on July 17, 2002, is available on the Internet at <http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874T1.htm>.

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147 CMI,^{7, 8} and (2) it includes the components suggested in the Action Plan and substantially
148 conforms to the formatting suggestions made in the Action Plan. Specifically, written CMI
149 should be:

- 150
- 151 • scientifically accurate
- 152 • unbiased in content and tone
- 153 • sufficiently specific and comprehensive
- 154 • presented in an understandable and legible format that is readily comprehensible to
- 155 consumers
- 156 • timely and up-to-date
- 157 • useful
- 158

159 Critical criteria, components, and formatting suggestions are in Chapter 3 (*Guidelines for Useful*
160 *Prescription Medication Information*) and Appendix G (*Specific Language and Format*
161 *Guidelines, with Samples*) of the Action Plan. This guidance provides FDA’s recommendations
162 to the private sector for implementing the Action Plan criteria.

163

164 The eight categories listed in the following table were developed by an expert panel,
165 subcontracted by NABP for FDA’s evaluation of CMI in 2001, by combining the Action Plan
166 criteria and components. FDA believes that this list provides the factors for determining whether
167 written medication information is useful. Written information that substantially satisfies each
168 Action Plan criterion listed in the table will be deemed *useful* and will count toward the
169 quantitative goals of Section 601 of Title VI of Public Law 104-180.

170

171 **Action Plan Criteria for Defining Useful Information**

172

Criterion	Description
1	Drug names, indications for use, and how to monitor for improvement
2	Contraindications and what to do if they apply
3	Specific directions about how to use and store the medicine, and overdose information
4	Specific precautions and warnings about the medicine
5	Symptoms of serious or frequent possible adverse reactions and what to do

⁷ FDA-approved drug products and labeling can be found on the Internet at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. However, this Web site does not list all FDA-approved products and labeling. We are working to make all approved labeling available soon.

⁸ Consistent with the Action Plan and acceptance by the Secretary, information beyond the FDA-approved labeling, such as patient-specific indications for use from scientific literature or provided by the prescriber is appropriate in customized patient information. FDA recommends that the source of such information be included in CMI.

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Criterion	Description
6	Certain general information, including encouraging patients to communicate with healthcare professionals, and disclaimer statements
7	Information that is scientifically accurate, unbiased in tone and content, and up-to-date
8	Information in an understandable and legible format that is readily comprehensible to consumers

173

174

175

B. Specific Recommendations for Each Action Plan Criterion

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177

Criterion 1: Drug Name, Indications for Use, and How to Monitor for Improvement

178

179

We recommend that the following information be included in the CMI to satisfy Criterion 1:

180

181

- Established name and brand name (e.g., the trademark or proprietary name) of the drug and the phonetic spelling (pronunciation) of the established name. FDA recommends also including the phonetic spelling of the brand name.⁹

182

183

184

185

- All FDA-approved indications listed in the PI for the medication. Information on unapproved indications should only be included in CMI customized for individual patients

186

187

188

189

- Information regarding how to monitor the effectiveness of the treatment by correctly interpreting physical reactions to the medicine, if this information is in the PI. This would include, for example, informing patients about when to call their healthcare provider if they do not notice signs of improvement.

190

191

192

193

194

Criterion 2: Contraindications and What to Do if They Apply

195

196

We recommend that the following information be included in the CMI to satisfy Criterion 2:

197

198

- Information about circumstances in which the medication should not be used for its labeled indication. Include all contraindications listed in the PI.

199

200

201

- Directions about what to do if any of the contraindications apply to the patient, such as contacting the healthcare provider before taking the medicine or discussing with him or her situations that would warrant discontinuing use of the medication. Include a general

202

203

⁹ The Action Plan contained an error in reference to established name and brand name. All marketed products have an established name (also known as the generic name), while not all products have a brand name. Therefore, if a brand name does not exist, the phonetic spelling of the established name would be used.

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204 statement such as, *Talk to your healthcare provider before taking this medicine if you*
205 *have any of these conditions.*

206

207 • Information on any contraindication that could result in serious injury or death if it is
208 disregarded.

209

210 • A statement of precaution about any circumstances (such as past or current medical
211 conditions or use of other medications, vitamins, or supplements) in which the use of the
212 medication could lead to serious injury or death.

213

214 *Criterion 3: Specific Directions About How to Use and Store the Medicine and Information*
215 *About Overdose*

216

217 We recommend that the following elements be addressed to satisfy Criterion 3:

218

219 • The CMI should be considered a stand-alone document in meeting this criterion. The
220 label and packaging of the dispensed medication may also contain such information (e.g.
221 name, strength, dosage, brief directions for use), but for the purposes of assessing
222 usefulness, should not be considered as part of CMI.

223

224 • If detailed instructions describing how to administer the medication (instructions for use)
225 are included in the manufacturer's patient labeling for the product (for example,
226 instructions for inhalers, injections, and patches), include a statement to alert the patient
227 to read the instructions for use contained in the package.

228

229 • A statement should be included in the CMI to stress the importance of adhering to the
230 dosing instructions prescribed by the healthcare provider.

231

232 • State the route of administration. Examples of information about the route of
233 administration are *skin use only* if a patch and *do not swallow* if a suppository.

234

235 • If specified in the PI, include information on how to use the medication, such as whether
236 to take it with or without food or water, times of day to take the medication, and any
237 other instructions, for example, statements such as (1) *Do not chew*, (2) *Do not split or*
238 *crush*, and (3) *Do not lie down for 30 minutes after taking this medicine*.

239

240 • Describe what patients can do if they miss a scheduled dose, if this information is in the
241 PI.

242

243 • State the risks to the patient of developing tolerance to or physical or psychological
244 dependence on the drug if this information is included in the PI. In the case of these
245 medicines, provide an explanation of tolerance, dependence, or addiction, and list the
246 physical and psychological signs of addiction and withdrawal.

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- 248 • State what to do in case of an overdose. If overdose is a significant issue for a particular
249 medication, include text describing signs of overdose so that patients can recognize the
250 symptoms. In all cases, we recommend that symptoms of overdose be directly followed
251 by instructions for what to do should these signs or symptoms occur, such as calling the
252 doctor or other emergency telephone number.
253
- 254 • Include storage instructions.
255

256 *Criterion 4: Specific Precautions and Warnings*

257

258 If the PI contains any boxed warnings that relate to important knowledge the consumer should
259 have or actions the consumer should take, we recommend that a prominently displayed statement
260 which is consistent with or derived from the boxed warnings be included in the CMI. FDA
261 believes that most boxed warnings have information that is relevant to the consumer.
262

263 We recommend that the CMI include all information stated in the PI regarding what precautions
264 the patient should take while using the drug to avoid negative consequences. For example, the
265 following information should be included:
266

- 267 • Drugs to avoid because of drug-drug interactions.
268
- 269 • Foods and other substances (e.g., dietary supplements) to avoid because of the potential
270 for interactions. Since the Action Plan was written, there has been increased awareness of
271 dietary supplement interactions with medications. If such interactions are included in the
272 PI, include them in the CMI in the same way as drug and food interactions.
273
- 274 • Patient activities and behavior to avoid. Examples of such activities include smoking
275 tobacco, drinking alcohol, being exposed to the sun, or driving a vehicle or operating
276 dangerous machinery. Sometimes a behavioral instruction is not given in the PI, but a
277 specific precaution or warning will imply that a certain behavior should be avoided. In
278 this circumstance, specify the behavior to be avoided. For example, if the PI states that
279 the medication has been shown to result in photosensitivity, then advise patients to avoid
280 sun exposure. If the PI states that the product can cause drowsiness, then advise patients
281 to avoid driving or operating heavy machinery until patients know how they will react to
282 the medication.
283
- 284 • Any risks to the mother and the fetus or the infant from use of the drug during pregnancy,
285 labor, or breast-feeding. If the risks are unknown, include a statement such as, *Talk to*
286 *your doctor if you are pregnant or breast-feeding. It is not known if the medicine will*
287 *affect your baby.*
288
- 289 • Specific risks to identifiable patient populations, such as children, elderly patients, people
290 with compromised immune systems, or people with impaired kidney or liver functioning,
291 if such information is in the PI. Provide enough detailed risk information for the
292 consumer to understand the significance of the hazard described.

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Criterion 5: Symptoms of Serious or Frequent Possible Adverse Reactions and What to Do

The most serious potential adverse reactions will most likely appear in the *Warnings* or *Precautions* sections of the PI; we recommend that this information be included in CMI. In addition, we recommend that CMI include a list of, at minimum, the symptoms of at least the 5 to 9 most frequently occurring (common) adverse reactions.

We recommend including a statement telling patients that the side effects given are not a complete list and instructing them to ask their doctor or pharmacist for more information.

Criterion 6: Certain General Information, Including Encouraging Patients to Communicate with Healthcare Professionals, and Disclaimers

We recommend that certain general information be contained in all CMI:

- A statement that the medicine should only be used by the patient for whom it is prescribed and should not be given to other people.
- The name of the publisher of the CMI.
- The date that the CMI was published or the date of the most recent revision or review for adequacy and accuracy of content.
- A disclaimer stating that the CMI is a summary and does not contain all possible information about the medicine.
- A statement encouraging discussion with a healthcare professional about the prescription medicine. A statement that the healthcare professional who prescribed the medicine has additional information about the medicine as well as about the patient’s specific health needs, and that the healthcare professional can provide this information to the patient and answer the patient’s questions. An example of a statement that covers both recommendations could be: *This leaflet summarizes the most important information about <insert medication name>. If you would like more information, talk with your doctor.*

Criterion 7: Information That Is Scientifically Accurate, Unbiased in Tone and Content, and Up-to-Date

Scientific accuracy is an essential characteristic of CMI. The entire CMI will be assessed for scientific accuracy and bias. The information in the CMI should be consistent with or derived from the PI, unless the CMI is customized for individual patients.

The text of the CMI should be unbiased in content and tone and should meet the accepted standards of scientific literature. That is, the text should be explanatory; neutral; without

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338 comparative adjectives, untruthful claims about the benefit of a product, or hyperbole; and
339 distinguished from any promotional or other information provided to the patient.

340
341 CMI should not promote a specific brand, manufacturer, or distributor for the purpose of
342 economic gain.

343
344 *Criterion 8: Information in an Understandable and Legible Format That Is Readily*
345 *Comprehensible to Consumers*

346
347 To be useful, CMI should be written in wording that is understandable. To meet the Action Plan
348 criterion of being understandable, we suggest that CMI be provided at the sixth to eighth grade
349 reading level. This can be achieved by using a validated readability instrument. We encourage
350 using plain language and looking at the message from the reader's point of view.

351
352 CMI should adhere to the criteria, components, and formatting suggestions in Chapter 3
353 (*Guidelines for Useful Prescription Medication Information*) and Appendix G (*Specific*
354 *Language and Format Guidelines, with Samples*) of the Action Plan, which “reflect widely
355 recognized standards used by designers and publishers of written information to ensure that the
356 materials are legible and readable.” We recommend that CMI be designed to ensure the
357 prominence of important information. It is helpful to use formats that distinguish between the
358 degree of seriousness of cautions or warnings. Information should be written clearly and
359 concisely, and complex terms should be avoided. Polysyllabic words could be replaced by
360 shorter, simpler words (e.g., *harmful* rather than *detrimental*), even if it takes several words to
361 get across a concept that can be expressed in a single, more complex term.

362
363 We recommend the following formatting:

- 364
- 365 • Use 10-point or larger type size.
 - 366
 - 367 • Do not use ornate typefaces and italics. Choose a bolder type over a thin version of the
368 same style.
 - 369
 - 370 • Use upper- and lower-case lettering, not all capitals.
 - 371
 - 372 • Use bold-face type or a box to call attention to important information, rather than
373 highlighting or underlining.
 - 374
 - 375 • Provide adequate space between letters, lines, and paragraphs. We suggest that text
376 generally have no more than –3 *Kerning* (space between letters). With 10-point type, 12-
377 point *leading* (space between lines) is recommended (at least 2.2 millimeters). Provide
378 adequate space between paragraphs and space above and below headings.
 - 379
 - 380 • Do not use a line length that is too long. In 10-point or 12-point type, optimal line length
381 is approximately 40 letters long.
 - 382

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- 383 • Select text color and paper that give a strong contrast. Black, dark blue, or brown ink on
384 white or pale yellow uncoated paper provides the best contrast. We suggest that other
385 combinations be avoided.
386
- 387 • Use short paragraphs and bullets where possible.
388

389 **C. Summary**
390

391 The components of useful information identified in the Action Plan are meant to be useful “as a
392 total package.” We suggest that the information be provided in the following order:
393

- 394 1. Personalized information in a box (if customized for individual patients)
395 2. Established name and brand name
396 3. What the medicine is used for
397 4. Do not take this medicine if you are...
398 5. How to take the medicine
399 6. Side effects include ...
400 7. General information
401

402 This list is not the only appropriate headings or order in which the headings should appear.
403 Moreover, information pertaining to each Action Plan criterion need not be organized under the
404 above-specified individual headings; they can be combined as appropriate.
405