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# Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names

## ***DRAFT GUIDANCE***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)**

**November 2008  
Labeling**

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*GIX*

# Guidance for Industry

## Contents of a Complete Submission for the Evaluation of Proprietary Names

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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 Drug Evaluation and Research (CBER)**

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***Contains Nonbinding Recommendations***

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42 **Guidance for Industry<sup>1</sup>**  
43 **Contents of a Complete Submission for the Evaluation of**  
44 **Proprietary Names**  
45  
46

47  
48 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current  
49 thinking on this topic. It does not create or confer any rights for or on any person and does not operate to  
50 bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of  
51 the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA  
52 staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call  
53 the appropriate number listed on the title page of this guidance.  
54

55  
56  
57 **I. INTRODUCTION**  
58

59 Accurate identification of medications is critical to preventing *medication errors*<sup>2</sup> and potential  
60 harm to the public. This guidance is intended to assist industry in the submission of a complete  
61 package of information that FDA will use in the assessment both of the safety aspects of a  
62 proposed *proprietary name*, to reduce medication errors, and of the promotional implications of  
63 a proposed name, to ensure compliance with other requirements for *labeling* and promotion

64 This guidance applies to proprietary name submissions for the following types of products:  
65

- 66 • Prescription drug products, including biologics, that are the subject of a new drug  
67 application (NDA), an abbreviated new drug application (ANDA), or a biologics license  
68 application (BLA), or that are currently the subject of an investigational new drug  
69 application (IND) in anticipation of submission in a marketing application.
- 70 • Nonprescription drug products that are the subject of an NDA or ANDA

71  
72 FDA's guidance documents, including this guidance, do not establish legally enforceable  
73 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should  
74 be viewed only as recommendations, unless specific regulatory or statutory requirements are  
75 cited. The use of the word *should* in Agency guidances means that something is suggested or  
76 recommended, but not required.  
77

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<sup>1</sup> This guidance has been prepared by the Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology, in the Center for Drug Evaluation and Research (CDER) in cooperation with the Advertising and Product Labeling Branch in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

<sup>2</sup> All terms presented in *bold italics* at first use in this guidance are defined in the Glossary.

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### 78 **II. BACKGROUND**

79  
80 On September 27, 2007, the reauthorization and expansion of the Prescription Drug User Fee Act  
81 (PDUFA IV) was signed into law as part of Public Law 110-85, 121 Stat. 823. The  
82 reauthorization of PDUFA significantly broadens and strengthens the Food and Drug  
83 Administration's (FDA) drug safety program, facilitating more efficient development of safe and  
84 effective new medications for the American public. As part of the reauthorization of PDUFA  
85 IV, FDA committed to certain performance goals in its goals letter.<sup>3</sup> In that letter, FDA stated  
86 that it would use user fees to implement various measures to reduce medication errors related to  
87 look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose  
88 designations, and error-prone label and packaging designs.

89  
90 Among these measures, FDA agreed to publish guidance on the contents of a complete  
91 submission package for a proposed proprietary name for a drug or biological product. FDA also  
92 agreed to performance goals for review of proprietary names submitted during the IND phase or  
93 with an NDA or BLA; the goals stipulate that a complete submission is required to begin the  
94 review clock.

#### 97 **A. Recommendations to Minimize Medication Errors**

98  
99 This guidance and other PDUFA IV proprietary name evaluation measures grow out of  
100 initiatives aimed at minimizing medication errors.

101  
102 In 2000, the Institute of Medicine (IOM) published a report entitled *To Err Is Human: Building*  
103 *a Safer Health System*.<sup>4</sup> The report stated that from 44,000 to 98,000 deaths occur yearly due to  
104 **medical errors**, making medical errors the eighth leading cause of death in the United States.<sup>5</sup>  
105 The report identified medication errors as the most common type of error in health care. Seven  
106 thousand (7,000) deaths annually were attributed to medication errors.<sup>6</sup> The IOM recommended  
107 that FDA

---

<sup>3</sup> See goals letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record, at <http://www.fda.gov/oc/pdufa4/pdufa4goals.html>. (goals letter).

<sup>4</sup> Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Institute of Medicine, National Academies Press: Washington DC. 2000.

<sup>5</sup> American Hospital Association. *Hospital Statistics*. Chicago. 1999. See also: Brennan TA, Leape LL, Laird NM, et al. Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I. *N Engl J Med*. 324:370-376, 1991; Leape LL, Brennan TA, Laird NM, et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. *N Engl J Med*. 324(6):377-384, 1991; Centers for Disease Control and Prevention (National Center for Health Statistics). Births and Deaths: Preliminary Data for 1998. *National Vital Statistics Reports*. 47(25):6, 1999, cited in *To Err Is Human*, p. 1.

<sup>6</sup> Phillips, DP, Christenfeld, N, and Glynn, LM. Increase in US Medication-Error Deaths between 1983 and 1993. *The Lancet*. 351:643-644, 1998, cited in *To Err Is Human*, p. 2.

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- 108           ● “develop and enforce standards for the design of drug packaging and labeling that  
109           will maximize safety in use” and  
110           ● “require pharmaceutical companies to test proposed drug names to identify and  
111           remedy potential sound-alike and look-alike confusion with existing drug names.”<sup>7</sup>  
112

113 In July 2006, the IOM published a report entitled *Preventing Medication Errors*. In this report,  
114 the IOM cited labeling and packaging issues as the cause of 33 percent of medication errors,  
115 including 30 percent of fatalities from medication errors.<sup>8</sup> Given the critical role of the *label* and  
116 labeling in the safe use of drug products, this statistic is not surprising. The container label,  
117 carton, and (for prescription drug products) professional insert labeling are the primary means  
118 by which practitioners and patients identify and make decisions about using the product. Carton  
119 and container labels communicate critical information including proprietary and *established*  
120 *name*, strength, dosage form, container quantity, and expiration date, and are particularly critical  
121 for nonprescription (over-the-counter (OTC)) products. For prescription products, the  
122 professional insert labeling is intended to communicate to practitioners all information relevant  
123 to the approved uses of the product, including the correct dosing and administration.  
124

125 The July 2006 IOM report stated that “Product naming, labeling, and packaging should be  
126 designed for the end user — the provider in the clinical environment and/or the consumer.”<sup>9</sup>  
127 The report also urged FDA to incorporate better principles of cognitive and human factors  
128 engineering to address issues concerning information presentation in labeling and  
129 nomenclature.<sup>10</sup>  
130

131 In addition to the IOM recommendations, the Secretary of Health and Human Services published  
132 a report titled *Bringing Common Sense to Health Care Regulation: Report of the Secretary’s*  
133 *Advisory Committee on Regulatory Reform* (November 2002). This report recommended that  
134 FDA adopt safe labeling practices for all FDA-regulated products to improve patient safety and  
135 decrease preventable adverse drug events.  
136

### **B. Medication-Use Systems**

137  
138  
139 Medication use within a health care organization can be viewed as a system with several  
140 components and processes, including:

- 141           ● inputs (patient and drug therapy information),  
142           ● throughputs (care provided), and

---

<sup>7</sup> This effort is also consistent with FDA’s May 10, 1999 report to the FDA Commissioner titled *Managing the Risks From Medical Product Use*, which underscored the importance of providing an adequate risk assessment associated with the use of drug products, including a mandate to reduce medication errors from proprietary name confusion.

<sup>8</sup> Aspden P, Wolcott JA, Bootman JL, Cronenwett LR, eds. *Preventing Medication Errors*. Institute of Medicine, The National Academies Press: Washington DC. 2006. Chapter 6: p. 275.

<sup>9</sup> IOM, *Preventing Medication Errors*. Chapter 6, Recommendation 4, p. 280.

<sup>10</sup> IOM, *Preventing Medication Errors*. Chapter 2, p. 61.

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- outputs (effective, efficient, and safe treatment).<sup>11</sup>

Depending on the setting and organization, there are many variables interacting within a **medication-use system**. These variables include, but are not limited to

- different processes and procedures,
- different types of health care providers involved,
- different patients,
- different products,
- different storage and dispensing conditions, and
- different available technologies.

The many variables and interactions within the medication-use system create ample opportunity for confusion and medication errors.

### **C. Proprietary Name Confusion and Medication Errors**

In the U.S. medication-use system, health care providers rely on the proprietary name as the critical identifier of the appropriate therapy in a market of thousands of products; therefore, accurate interpretation of the product name is essential to ensure that the correct product is procured, prescribed, prepared, dispensed, and administered to the patient. Products “might be prone to error in use due to sound-alike or look-alike names, unclear labeling, or poorly designed packaging.”<sup>12</sup> Product names that look and/or sound alike can lead to medication error and potential harm to patients by increasing the risk that health care providers could misunderstand the product name, prescribe the wrong product, dispense and/or administer the wrong product, or dispense a product incorrectly. Similarly, product names that look and/or sound alike may lead consumers to select or administer their nonprescription medication incorrectly.

### **D. FDA’s Approach to the Evaluation of Proposed Proprietary Names**

As part of its premarket review of products that are the subject of an NDA, BLA, or ANDA, FDA evaluates both safety and promotional aspects of the product’s proposed proprietary name.<sup>13</sup>

FDA’s safety review of a proposed proprietary name focuses on the prevention of medication errors. Accurate identification of medications is critical to preventing medication errors and potential harm to the public. Because medication error due to product misidentification or confusion can occur at any point in the medication-use system, in its evaluation of a proposed proprietary name, FDA considers the potential for confusion throughout the entire U.S.

---

<sup>11</sup> *Medication Use: A Systems Approach to Reducing Errors*. Joint Commission on Accreditation of Healthcare Organizations, 1998. p. 6.

<sup>12</sup> IOM, *To Err Is Human*, p. 136.

<sup>13</sup> Legal authorities are explained in the next section.

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181 medication-use system, including product procurement, prescribing and ordering, dispensing,  
182 administration, and monitoring the effects of the medication.<sup>14</sup>

183  
184 The overall medication error safety assessment is based on the findings of a Failure Modes and  
185 Effects Analysis (FMEA) of the proprietary name. FMEA is a systematic tool for evaluating a  
186 process and identifying where and how it might fail.<sup>15</sup> FMEA is used to analyze whether a  
187 proposed proprietary name has look- or sound-alike similarities to the names of existing products  
188 that could cause confusion and subsequently lead to medication errors in the clinical setting.

189  
190 To fully assess the safety of proprietary names, it is essential that certain ***product characteristics***  
191 be considered in the overall risk assessment. The proprietary name and product characteristics  
192 provide the framework for how product variables will interact within the medication-use system  
193 and provide the context for the verbal and written communication of the drug name. Product  
194 characteristics can act together with the orthographic and phonologic attributes of the proprietary  
195 name (1) to increase the risk of confusion when there is an overlap in product characteristics  
196 among two or more products, or (2) in some instances, to decrease the risk of confusion by  
197 helping to differentiate products through dissimilarity. FDA considers product characteristics  
198 throughout the risk assessment because the product characteristics provide a context for  
199 communication of the proprietary name and ultimately determine the use of the product in the  
200 usual clinical practice setting.

201  
202 FDA considers typical product characteristics that could lead to confusion with other products,  
203 including, but not limited to, the following:

- 204 ● established name of the product
- 205 ● proposed indication
- 206 ● dosage form
- 207 ● route of administration
- 208 ● strength
- 209 ● unit of measure
- 210 ● dosage units
- 211 ● recommended dose
- 212 ● typical quantity or volume
- 213 ● frequency of administration
- 214 ● product packaging
- 215 ● storage conditions
- 216 ● patient population
- 217 ● prescriber population

218  
219 FDA staff use the product characteristics in the analysis of a proprietary name to anticipate the  
220 clinical setting(s) in which the product is likely to be used.

221  
222 In addition to the safety review, FDA conducts a promotional review of proposed proprietary  
223 names. This promotional review considers whether the name functions to overstate the efficacy,

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<sup>14</sup> IOM, *Preventing Medication Errors*.

<sup>15</sup> Institute for Healthcare Improvement (IHI). *Failure Modes and Effects Analysis*. Boston. IHI:2004.

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224 minimize the risk, broaden the indication, or make unsubstantiated superiority claims for the  
225 product, or is overly “fanciful” by misleadingly implying unique effectiveness or composition, or  
226 is otherwise false or misleading. (See 21 U.S.C 321(n), 352(a) and (n); see also 21 CFR 201.10  
227 (c)(3), 202.1(e)(5)(i), and (e)(6)(i).)  
228

### **E. Regulatory Authority**

229  
230  
231 FDA’s authority to obtain submissions that address proprietary names and regulate proprietary  
232 names is based on the Federal Food, Drug, and Cosmetic Act (the Act) and Agency regulations.  
233 Among these authorities are the following:  
234

235 Proprietary names are used in a product’s labels and labeling, as well as in other promotional  
236 materials. Under section 502(a) of the Act (21 U.S.C. 352(a)), a drug, including a biologic, is  
237 misbranded if its labeling is false or misleading in any particular. In addition, section 351(b) of  
238 the Public Health Service Act (42 U.S.C. 262(b)) prohibits falsely labeling or marking any  
239 package or container of any biological product.<sup>16</sup> Under section 505(d)(7) of the Act (21 U.S.C.  
240 355(d)(7)), an NDA or ANDA shall not be approved if the drug's labeling is false or misleading  
241 in any particular. (See also 21 CFR 314.125 (b)(6) and (b)(8) (grounds for disapproval of NDA  
242 or ANDA including that proposed labeling is false or misleading in any particular or that  
243 labeling does not comply with requirements of 21 CFR part 201); 21 CFR 314.105(c)(requiring  
244 compliance with statutory standards for labeling in order to approve an NDA or ANDA); 21  
245 CFR 601.4(b)(BLA shall be denied if establishment or product does not meet requirements  
246 specified in FDA regulations, including requirements of part 201).) NDAs, ANDAs, and BLAs  
247 must contain labeling and all other information about the drug that is pertinent to evaluation of  
248 the application, to provide FDA with a basis on which to make the required findings for approval  
249 or licensure. (See 21 CFR 314.50; 21 CFR 601.2.)  
250

251 Section 201(n) (21 U.S.C. 321(n)) indicates that when a drug is alleged to be misbranded  
252 because its labeling or advertising is misleading, the determination of whether the labeling or  
253 advertising is misleading should take into account (among other things):  
254

255 not only representations made or suggested by statement, word, design, device, or any  
256 combination thereof, but also the extent to which the labeling or advertising fails to  
257 reveal facts material in the light of such representations or material with respect to  
258 consequences which may result from the use of the article to which the labeling or  
259 advertising relates under the conditions of use prescribed in the labeling or advertising  
260 thereof or under such conditions of use as are customary or usual.  
261

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<sup>16</sup> See also section 502(n) of the Act, 21 U.S.C. 352(n) (advertising of a prescription drug misbrands unless it contains a true statement of other information in brief summary relating to side effects, contraindications, and effectiveness); 21 CFR 202.1(e)(5)(addressing "true statement" requirement); 21 CFR 202.1(k) (prescription drugs misbranded if not compliant with section 502(n) of the act and implementing regulations).

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262 In addition to this general principle, applicable to proprietary names, several FDA regulations  
263 specifically address ways in which the name of a drug may render its labeling misleading. For  
264 example, FDA regulations at 21 CFR 201.6(b) state:

265  
266 The labeling of a drug which contains two or more ingredients may be misleading by  
267 reason, among other reasons, of the designation of such drug in such labeling by a name  
268 which includes or suggests the name or one or more but not all such ingredients, even  
269 though the names of such ingredients are stated elsewhere in the labeling.

270  
271 Likewise, 21 CFR 201.10(c) states that the labeling of a drug may be misleading by reason of:

272  
273 (3) The employment of a fanciful proprietary name for a drug or ingredient in such a  
274 manner as to imply that the drug or ingredient has some unique effectiveness or  
275 composition when, in fact, the drug or ingredient is a common substance, the limitations  
276 of which are readily recognized when the drug or ingredient is listed by its established  
277 name.

278 . . . .

279  
280 (5) Designation of a drug or ingredient by a proprietary name that, because of similarity  
281 in spelling or pronunciation, may be confused with the proprietary name or the  
282 established name of a different drug or ingredient.

283  
284 Based on these authorities, ***applicants*** must submit, and FDA reviews, proprietary names as part  
285 of NDAs, ANDAs, and BLAs. To further their business goals, many drug manufacturers prefer  
286 to have FDA evaluate a proposed proprietary name even earlier in the drug development process,  
287 when possible. Consequently, FDA permits manufacturers, if they wish, to seek FDA's initial  
288 evaluation of a proposed proprietary name prior to the submission of the marketing application,  
289 while the product remains under an IND. However, to ensure that resources are not used to  
290 evaluate proposed proprietary names for products that will not be viable candidates for an NDA,  
291 ANDA, or BLA, or for which proposed indications are not yet sufficiently clear to form the basis  
292 of an evaluation of a name for potential medication errors, FDA does not evaluate proprietary  
293 names until products have completed phase 2 trials.

### **III. CONTENTS OF A COMPLETE SUBMISSION FOR EVALUATION OF PROPOSED PROPRIETARY NAMES**

294  
295  
296  
297  
298  
299 This section describes the information FDA recommends that a ***sponsor*** or applicant include in  
300 order to ensure that the Agency can conduct a complete review of a proposed proprietary name.  
301 As described in section II.D, FDA evaluates orthographic and phonological characteristics of the  
302 proposed name in connection with product characteristics, to evaluate the acceptability of the  
303 proposed proprietary name. This section provides recommendations applicable to submissions  
304 for products with proposed labels and labeling, and for products for which proposed labels and  
305 labeling have not yet been developed. In accordance with the PDUFA goals, the review clock  
306 for a proprietary name evaluation will not begin if a submission is not complete. FDA will notify  
307 the applicant or sponsor in writing if it considers a submission to be incomplete.  
308

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### 309 **A. General Information**

310

311 Each submission should be identified as follows:

312

- 313 • For proprietary name reviews, include the statement “**REQUEST FOR PROPRIETARY**  
314 **NAME REVIEW**” in bold, capital letters on the first page of the submission.  
315
- 316 • For proprietary names that applicants and sponsors are submitting for reconsideration  
317 following an initial rejection of their proposed names, include the statement “**REQUEST**  
318 **FOR RECONSIDERATION OF PROPRIETARY NAME**” in bold, capital letters on the  
319 first page of the submission.  
320

321 A proprietary name evaluation submission for a drug product, including a biologic, that is the  
322 subject of an IND should include FDA Form 1571; a proprietary name evaluation submission for  
323 a drug product, including a biologic, that is the subject of an NDA, ANDA, or BLA should  
324 include FDA Form 356h. The forms should provide information including the following:  
325

326

- 326 • Proposed first choice proprietary name
- 327 • Application number (BLA/NDA/ANDA/IND)
- 328 • Applicant or sponsor contact information including the company name, name and title of  
329 the contact person, address, phone number, fax number, and e-mail address
- 330 • Identification of the submission as a Request for Proprietary Name Review, Request for  
331 Reconsideration of Proprietary Name, or Amendment to a Request for Proprietary Name  
332 Review.<sup>17</sup>
- 333 • A list of contents in the submission

334

### 335 **B. Proposed Proprietary Name**

336

337 All submissions should include the following information about the proposed proprietary name.

338

#### 339 *1. Primary and Alternate Proprietary Name*

340

341 The applicant or sponsor should propose up to two proprietary names for review in a submission  
342 and should specify the first choice. The alternate name will be evaluated only in the event the  
343 primary name is found to be unacceptable.  
344

344

#### 345 *2. Intended Pronunciation of the Proposed Proprietary Name*

346

347 Although FDA evaluates the various pronunciations of a proposed name to reflect the variations  
348 that might be observed in clinical practice, consideration is given to the pronunciation of the

---

<sup>17</sup> On FDA Form 1571, we recommend that you include this information under Box 11, by checking "Other" and providing the applicable description in the accompanying box. On FDA Form 356h, we recommend you include this information in response to the question on "Type of Submission," by checking "Other" and providing the applicable description in the accompanying box.

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349 name that the applicant or sponsor will promote, as this may influence pronunciation of the name  
350 in practice.

351

### 352 **3. *Derivation of Proprietary Name***

353

354 The submission should include an explanation of the derivation of the proposed proprietary  
355 name, if any.

356

### 357 **4. *Intended Meaning of Proprietary Name Modifiers (e.g., prefix, suffix)***

358

359 A modifier, such as a prefix or suffix, in the proprietary product name might suggest different  
360 meanings to health care professionals and consumers, which could potentially lead to product  
361 confusion. When an applicant or sponsor submits a product name with a modifier (for example,  
362 with the prefix Lo- or the suffix XR), the submission should include the intended meaning of the  
363 modifier, the rationale for the modifier, and any studies that have been conducted to support the  
364 use of the modifier.

365

### 366 **5. *Pharmacologic/Therapeutic Category***

367

368 The submission should include the pharmacologic/therapeutic category under which the product  
369 with the proposed proprietary name will be classified.

370

## 371 **C. *Additional Information about the Product***

372

373 This section describes what should be included in a submission when a product has a proposed  
374 label and labeling, and what should be included in a submission when a product does not yet  
375 have a proposed label and labeling.

376

### 377 **1. *Submission for a Product That Has Proposed Labels and Labeling***

378

#### 379 **a. *Proposed Labeling***

380

381 The submission should include a copy of the proposed labeling in color and reflecting the  
382 presentation that will be used in the marketplace. In the case of a prescription product, the  
383 professional labeling, also referred to as physician labeling or the package insert, provides  
384 important information for FDA's evaluation of proprietary names and other factors in association  
385 with the name that can contribute to product confusion. If a proposed patient package insert or  
386 proposed Medication Guide is available, it should also be included. See section III.C.2 of the  
387 guidance for a list of information that should be provided if the submission does not include the  
388 proposed labeling.

389

#### 390 **b. *Container Labels and Labeling***

391

392 The submission should include the proposed container label and other proposed external labeling  
393 or packaging, such as carton labels, pouches or overwraps, and sample labels. The submission  
394 should indicate the size of the actual label and provide the label, labeling, and packaging in color

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395 and reflect the presentation that will be used in the marketplace, so that FDA can assess the  
396 presentation of the product name and information. For small labels and labeling, please provide  
397 the original copy and a larger copy for ease of review.

398  
399 FDA will evaluate the proposed container labels and other proposed external labeling to identify  
400 potential problems with the proposed design or presentation of information that could contribute  
401 to confusion in a real world environment and lead to medication errors, where coupled with some  
402 similarity in proprietary names. For example:

- 403  
404 ● If critical information, such as the drug name and concentration, is not displayed prominently  
405 or is masked by more prominent but less critical information, these factors could contribute  
406 to confusion and possible medication errors.
- 407  
408 ● If product names are obscured by a logo or are illegible because of the font or color of the  
409 text, these factors could lead to name confusion or product selection errors.
- 410  
411 ● The similar appearance of labels or labeling among different drugs or different dosage  
412 strengths of drugs could contribute to selection of an incorrect drug or product strength where  
413 product names are similar.

414  
415 The possibility of this type of error is increased when products have similar names.

### 416 417 2. *Submission for a Product Without Proposed Labeling*

418  
419 If the proposed labeling is not available at the time of the proprietary name submission, the  
420 following information should be provided for FDA's evaluation. (This information is normally  
421 contained in professional labeling.)

#### 422 423 a. Established Name

424  
425 The submission should include the established name. An established name could contribute to  
426 product name confusion. For instance, if the established name itself is similar in appearance or  
427 pronunciation to the proprietary or established names of existing products, it may compound the  
428 potential for confusion if the proposed proprietary name of the product is also similar to other  
429 names. In addition, the established name can factor into the choice of product storage location.  
430 For example, certain institutions store medications by established name, not proprietary name.  
431 Having the established name thus helps FDA to determine what other product names will likely  
432 be displayed on the pharmacy shelf in close proximity to the proposed proprietary name.

#### 433 434 b. Prescription Status

435  
436 Prescription status affects storage location and clinical conditions of use. Therefore, the  
437 submission should include information about whether the product will be available without a  
438 prescription and/or by prescription. If the product is a controlled substance listed in schedule II,  
439 III, IV, or V of the Federal Controlled Substances Act or implementing regulations, the

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440 submission should also include the assigned schedule (e.g., schedule II). The submission should  
441 note if product scheduling is pending.

442

443 c. Dosage Form(s)

444

445 The submission should include the finished dosage form, an important product characteristic for  
446 correct prescribing, dispensing, use, and storage of a product.

447

448 d. Product Strength(s)

449

450 The submission should include all proposed product strengths, because product strength is an  
451 important consideration when prescribing and dispensing a product. Product strength  
452 information is also important when determining potential confusion with other products and/or  
453 product line extensions. For instance, errors in selection of a wrong product can occur because  
454 of overlapping strengths between products that are available in multiple dosage formulations.  
455 Errors can also occur in selecting the correct product strength if the strengths are not presented  
456 clearly on the label or labeling.

457

458 e. Proposed Indication(s) for Use

459

460 The proposed submission should include the indications for use, which provide insight into the  
461 prescribing and patient populations and potential clinical care environments in which the product  
462 will be used and stored.

463

464 f. Route(s) of Administration

465

466 The submission should include the route of administration, which provides additional context to  
467 product prescribing, storage, dispensing, clinical care environment, and patient use. For instance,  
468 the route of administration can influence the environment in which the product is prescribed  
469 (e.g., inpatient setting vs. outpatient setting) and prepared for dispensing (e.g., sterile vs.  
470 nonsterile) and ultimately the finished dosage form (e.g., vial, IV admixture bag, tablet).  
471 Similarities and/or dissimilarities in the routes of administration can affect the potential for  
472 medication errors.

473

474 g. Usual Dosage, Frequency of Administration, Dosing Interval, Maximum  
475 Daily Dose

476

477 The submission should include information about the usual dosage, including the frequency of  
478 administration, the specific dosing interval, and the maximum daily dose. Similarities to or  
479 overlaps with other products in any of these areas can contribute to potential medication errors.

480

481 h. Dosing in Specific Populations

482

483 The submission should include a description of dosing modifications that are dependent on renal  
484 and/or hepatic function, age, or gender. This information provides insight into additional areas

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485 of potential overlap or similarity with other product lines or products in dosing or frequency of  
486 administration.

487

488 i. Instructions for Use

489

490 The submission should include a detailed description of and step-by-step instructions for product  
491 use, if applicable, such as instructions for preparation and administration of IV products. The  
492 description should communicate whether the product will be self-administered by the patient or  
493 will require a skilled health professional to administer it. Instructions for use information can  
494 help identify similarities with other products that, in combination with proprietary name  
495 similarities, could lead to product confusion.

496

497 j. Storage Requirement

498

499 The submission should include the storage requirement for the product both pre- and post-  
500 dispensing. Storing products with similar names in similar locations (for example, in a  
501 refrigerator) can contribute to medication errors in all levels of the medication-use system  
502 (warehouse, pharmacy, clinical care environment, or patient home).

503

504 k. How Supplied and Packaging Configuration

505

506 The submission should include information detailing how the product will be supplied and  
507 packaged. This information should include a description of the proposed product packaging, such  
508 as blister packs or inhalers. Product packaging is used by health care practitioners and  
509 consumers to select and administer the correct medication and dose and is the primary means by  
510 which practitioners and patients identify and use the product. The submission should also  
511 include the product strength, net quantity/size of all containers, and whether the product will be  
512 supplied in any physician samples or starter packs. This information also helps to determine the  
513 potential for confusion of the proposed product with other products. For instance, selection of  
514 the wrong product can occur where products with similar names also have similar net quantity,  
515 product strength, and/or packaging.

516

### **D. Information about Product Dispensing and Delivery**

517

518 All submissions should contain the following information about product dispensing and delivery  
519 for FDA to complete a proprietary name review.

520

521 1. *Likely Care Environment(s) for Dispensing and Use*

522

523 The submission should include a list of all the likely care environments for dispensing and use of  
524 the product. For example, include information about whether the product is expected to be used  
525 in an inpatient/hospital setting, long-term care facility, clinic, doctor's office, or home. Also  
526 describe the proposed distribution of the product, such as whether the product is to be dispensed  
527 from a retail or hospital pharmacy setting or distributed directly from the manufacturer or select  
528 wholesaler. This information provides insight into where an error might occur in the medication-  
529 use system.

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### **2. *Delivery System***

If applicable, we recommend that the submission include a model and instructions for use of the product delivery system (e.g., transdermal patch) or product device (e.g., pen injector, inhaler). If no model is available, the submission should include a detailed description of the delivery system or device. Submitting this information allows FDA to assess the actual use of the product and identify possible similarities to a different product with a similar name.

### **3. *Measuring Device***

If the product is to be dispensed with a measuring device (such as a calibrated dosing cup), we recommend that the submission include the device. If no sample device is available, you should include a description of the device, including its measuring calibration and any text or graphics to be printed on the device. Submitting the measuring device allows FDA to assess whether products with similar names could be subject to product confusion and medication error based on similarities in dosing and administration or in overall appearance.

### **E. *Assessments of Proprietary Name, Packaging, and/or Labeling***

FDA encourages applicants to include any assessments of the proprietary name, packaging, and/or labeling that were conducted or commissioned by the applicant or sponsor. Such research is often helpful in identifying potential problems with the nomenclature and labeling of products and would aid the Agency's review of the proprietary name, packaging, and labeling of a proposed product. However, FDA does not consider a submission incomplete because this information is not provided.

## **IV. WHEN AND WHERE TO SEND A SUBMISSION FOR A PROPOSED PROPRIETARY NAME REVIEW**

FDA generally encourages applicants and sponsors to submit their requests for FDA review of proposed proprietary names as soon as they have the recommended supporting information as described in this guidance. However, as explained in section II.E, if the request is submitted at the IND stage, it should be done no earlier than at the end of phase 2 of the IND process. Submissions may be in paper or electronic format. For paper submissions, the applicant or sponsor should submit three (3) copies of the submission to the same address as the original application with which the proprietary name is associated. For electronic submissions, see section IV.C below.

Applicants and sponsors should include on the first page of the submission the appropriate statement "**REQUEST FOR PROPRIETARY NAME REVIEW**" or "**REQUEST FOR RECONSIDERATION OF PROPRIETARY NAME**" in bold capital letters.

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### **A. Drug Products, Including Biologics, That Are the Subject of an IND, NDA, or BLA — Paper Submission**

#### *1. Submissions for Proposed Proprietary Names for Prescription Drugs, Including Biologics, That Are the Subject of an IND, NDA, or BLA Reviewed by CDER*

Center for Drug Evaluation and Research  
Food and Drug Administration  
Document and Records Section  
5901-B Ammendale Rd  
Beltsville, MD 20705-1266

#### *2. Submissions for Proposed Proprietary Names for Prescription Drugs, Including Biologics, That Are the Subject of an IND, NDA, or BLA Reviewed by CBER*

FDA/CBER  
Document Control Center, HFM-99  
1401 Rockville Pike, Suite 200N  
Rockville, MD 20852-1448

#### *3. Submissions for Proposed Proprietary Names for Nonprescription Drugs That Are the Subject of an NDA*

DHHS/FDA/CDER/ONP  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

### **B. Drugs Products That Are the Subject of an ANDA — Paper Submission**

Center for Drug Evaluation and Research  
Food and Drug Administration  
Document and Records Section  
5901-B Ammendale Rd  
Beltsville, MD 20705-1266

### **C. Electronic Submissions**

Applicants and sponsors who want to provide a proposed proprietary name submission electronically to CDER or CBER should refer to the FDA Web site “Electronic Common Technical Document (eCTD)” at <http://www.fda.gov/cder/regulatory/ersr/ectd.htm> and at <http://www.fda.gov/cber/esub/esub.htm>. Refer specifically to the following documents on that Web page:

- Guidance for industry on *Providing Regulatory Submissions in Electronic Format — Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*

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- 621 • eCTD Backbone File Specification for Module 1
- 622 • FDA eCTD Table of Contents Headings and Hierarchy
- 623
- 624 Applicants and sponsors are encouraged to use the Electronic Submissions Gateway
- 625 (ESG) to submit regulatory information. For information on the use of the ESG, refer to
- 626 <http://www.fda.gov/esg/>.
- 627
- 628

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### GLOSSARY

Because this guidance covers a wide range of products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), we have defined, for purposes of this document, a number of terms used in the guidance to enhance comprehension and avoid potential confusion.

**Applicant or sponsor:** The entity that submits a proposed proprietary name submission for the following types of products:

- Prescription drugs products (including biologics) that are the subject of an NDA (21 CFR 314.3(b)), a BLA (21 CFR 601.2), or an ANDA (21 CFR 314.92), or that are currently the subject of an IND (21 CFR 312.3(b)) in anticipation of submission in a marketing application
- Nonprescription drug products that are the subject of an NDA (21 CFR 314.3(b)) or ANDA (21 CFR 314.92)

**Established name:** The official name of the drug as defined under section 502(e)(3) of the Act (21 U.S.C. 352(e)(3)) and further described under 21 CFR 299.4, Established names for drugs; also known as “proper name” for biologics (see section 351(a)(1)(B)(ii) of the Public Health Service Act, 42 U.S.C. 262(a)(1)(B)(ii)). The established name is usually the name that has been derived by the U.S. Adopted Names Council (USAN). It is often the generic or common name of a product and can usually be found in the United States Pharmacopeia.

**Label:** As defined in section 201(k) of the Act, the term *label* means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

**Labeling:** As defined in section 201(m) of the Act, the term *labeling* means “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” Labeling includes outside containers, or wrappers, and package liners.

**Medical error:** The Institute of Medicine defines medical error as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.”<sup>18</sup> Types of errors include diagnostic, treatment, preventive, and other (such as failure of communication, equipment, or system).<sup>19</sup>

<sup>18</sup> IOM, *To Err is Human*. Chapter 1, p. 1.

<sup>19</sup> Leape, L, Lawthers, AG, Brennan, TA, et al. Preventing Medical Injury. *Qual Rev Bull*. 19(5):144-149, 1993, cited in *To Err is Human*, p. 1.

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671 **Medication error:** The National Coordinating Council for Medication Error Reporting and  
672 Prevention describes *medication error* as

673 any preventable event that may cause or lead to inappropriate medication use or  
674 patient harm while the medication is in the control of the health care professional,  
675 patient, or consumer. Such events may be related to professional practice, health  
676 care products, procedures, and systems, including prescribing; order  
677 communication; product labeling, packaging, and nomenclature; compounding;  
678 dispensing; distribution; administration; education; monitoring; and use.<sup>20</sup>  
679

680 **Medication-use system:** The Institute of Medicine describes *medication-use system* as the  
681 system that

682 encompasses the continuum of (1) prescribing by the clinician (or self-  
683 prescribing), followed by transcribing; (2) preparing and dispensing by the  
684 pharmacist; (3) administering by the provider or consumer (self-care); and (4)  
685 monitoring for therapeutic and adverse effects (by nurse, surrogate, or self).  
686 Each of these steps includes critical control points at which decisions and actions  
687 can contribute to safety or errors.<sup>21</sup>  
688

689 **Product characteristics:** The physical characteristics of the product itself (i.e., dosage form,  
690 strength, active ingredient) and environment in which the product is used, including but not  
691 limited to the established name, label, labeling, container, facility, storage conditions, who  
692 prescribes and administers the product, patient population, and other conditions of use.  
693

694 **Proprietary name:** The trademark, trade name, or brand name.  
695  
696  
697

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<sup>20</sup> National Coordinating Council for Medication Error Reporting and Prevention Web site,  
<http://www.nccmerp.org/aboutMedErrors.html>.

<sup>21</sup> IOM, *Preventing Medication Errors*, Chapter 2, p. 67.

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42 **Guidance for Industry<sup>1</sup>**  
43 **Contents of a Complete Submission for the Evaluation of**  
44 **Proprietary Names**  
45  
46

47  
48 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current  
49 thinking on this topic. It does not create or confer any rights for or on any person and does not operate to  
50 bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of  
51 the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA  
52 staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call  
53 the appropriate number listed on the title page of this guidance.  
54

55  
56  
57 **I. INTRODUCTION**  
58

59 Accurate identification of medications is critical to preventing *medication errors*<sup>2</sup> and potential  
60 harm to the public. This guidance is intended to assist industry in the submission of a complete  
61 package of information that FDA will use in the assessment both of the safety aspects of a  
62 proposed *proprietary name*, to reduce medication errors, and of the promotional implications of  
63 a proposed name, to ensure compliance with other requirements for *labeling* and promotion

64 This guidance applies to proprietary name submissions for the following types of products:  
65

- 66 • Prescription drug products, including biologics, that are the subject of a new drug  
67 application (NDA), an abbreviated new drug application (ANDA), or a biologics license  
68 application (BLA), or that are currently the subject of an investigational new drug  
69 application (IND) in anticipation of submission in a marketing application.
- 70 • Nonprescription drug products that are the subject of an NDA or ANDA  
71

72 FDA's guidance documents, including this guidance, do not establish legally enforceable  
73 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should  
74 be viewed only as recommendations, unless specific regulatory or statutory requirements are  
75 cited. The use of the word *should* in Agency guidances means that something is suggested or  
76 recommended, but not required.  
77

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<sup>1</sup> This guidance has been prepared by the Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology, in the Center for Drug Evaluation and Research (CDER) in cooperation with the Advertising and Product Labeling Branch in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

<sup>2</sup> All terms presented in *bold italics* at first use in this guidance are defined in the Glossary.

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### 78 **II. BACKGROUND**

79  
80 On September 27, 2007, the reauthorization and expansion of the Prescription Drug User Fee Act  
81 (PDUFA IV) was signed into law as part of Public Law 110-85, 121 Stat. 823. The  
82 reauthorization of PDUFA significantly broadens and strengthens the Food and Drug  
83 Administration's (FDA) drug safety program, facilitating more efficient development of safe and  
84 effective new medications for the American public. As part of the reauthorization of PDUFA  
85 IV, FDA committed to certain performance goals in its goals letter.<sup>3</sup> In that letter, FDA stated  
86 that it would use user fees to implement various measures to reduce medication errors related to  
87 look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose  
88 designations, and error-prone label and packaging designs.

89  
90 Among these measures, FDA agreed to publish guidance on the contents of a complete  
91 submission package for a proposed proprietary name for a drug or biological product. FDA also  
92 agreed to performance goals for review of proprietary names submitted during the IND phase or  
93 with an NDA or BLA; the goals stipulate that a complete submission is required to begin the  
94 review clock.

95  
96

#### 97 **A. Recommendations to Minimize Medication Errors**

98

99 This guidance and other PDUFA IV proprietary name evaluation measures grow out of  
100 initiatives aimed at minimizing medication errors.

101

102 In 2000, the Institute of Medicine (IOM) published a report entitled *To Err Is Human: Building*  
103 *a Safer Health System*.<sup>4</sup> The report stated that from 44,000 to 98,000 deaths occur yearly due to  
104 **medical errors**, making medical errors the eighth leading cause of death in the United States.<sup>5</sup>  
105 The report identified medication errors as the most common type of error in health care. Seven  
106 thousand (7,000) deaths annually were attributed to medication errors.<sup>6</sup> The IOM recommended  
107 that FDA

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<sup>3</sup> See goals letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record, at <http://www.fda.gov/oc/pdufa4/pdufa4goals.html>. (goals letter).

<sup>4</sup> Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Institute of Medicine, National Academies Press: Washington DC. 2000.

<sup>5</sup> American Hospital Association. *Hospital Statistics*. Chicago. 1999. See also: Brennan TA, Leape LL, Laird NM, et al. Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I. *N Engl J Med*. 324:370-376, 1991; Leape LL, Brennan TA, Laird NM, et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. *N Engl J Med*. 324(6):377-384, 1991; Centers for Disease Control and Prevention (National Center for Health Statistics). Births and Deaths: Preliminary Data for 1998. *National Vital Statistics Reports*. 47(25):6, 1999, cited in *To Err Is Human*, p. 1.

<sup>6</sup> Phillips, DP, Christenfeld, N, and Glynn, LM. Increase in US Medication-Error Deaths between 1983 and 1993. *The Lancet*. 351:643-644, 1998, cited in *To Err Is Human*, p. 2.