Guidance for Industry

Contents of a Complete Submission for the Evaluation of Proprietary Names

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Carol Holquist 301-796-2360 (CDER), or (CBER) Ele Ibarra-Pratt at 301-827-3028 (CBER).

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

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
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Center for Drug Evaluation and Research (CDER)
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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

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

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

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

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.

[1] 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.

[2] All terms presented in ***bold italics*** at first use in this guidance are defined in the Glossary.

II. BACKGROUND

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

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

A. Recommendations to Minimize Medication Errors

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

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

[3] 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).

[4] 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.

[5] 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.

[6] 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.

- "develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use" and
- "require pharmaceutical companies to test proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names."[7]

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

The July 2006 IOM report stated that "Product naming, labeling, and packaging should be designed for the end user — the provider in the clinical environment and/or the consumer."[9] The report also urged FDA to incorporate better principles of cognitive and human factors engineering to address issues concerning information presentation in labeling and nomenclature.[10]

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

B. Medication-Use Systems

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

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

[7] 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.

[8] 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.

[9] IOM, *Preventing Medication Errors*. Chapter 6, Recommendation 4, p. 280.

[10] IOM, *Preventing Medication Errors.* Chapter 2, p. 61.

- outputs (effective, efficient, and safe treatment).[11]

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."[12] 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.[13]

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.

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[11] *Medication Use: A Systems Approach to Reducing Errors*. Joint Commission on Accreditation of Healthcare Organizations, 1998. p. 6.

[12] IOM, *To Err Is Human*, p. 136.

[13] Legal authorities are explained in the next section.

medication-use system, including product procurement, prescribing and ordering, dispensing, administration, and monitoring the effects of the medication.[14]

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

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

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

- established name of the product
- proposed indication
- dosage form
- route of administration
- strength
- unit of measure
- dosage units
- recommended dose
- typical quantity or volume
- frequency of administration
- product packaging
- storage conditions
- patient population
- prescriber population

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

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

[14] IOM, *Preventing Medication Errors*.

[15] Institute for Healthcare Improvement (IHI). *Failure Modes and Effects Analysis*. Boston. IHI:2004.

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

E. Regulatory Authority

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

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

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

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

[16] 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).

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

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

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

> (3) The employment of a fanciful proprietary name for a drug or ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.
> . . . .
>
> (5) Designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

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

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

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

A. General Information

Each submission should be identified as follows:

- For proprietary name reviews, include the statement "**REQUEST FOR PROPRIETARY NAME REVIEW**" in bold, capital letters on the first page of the submission.

- For proprietary names that applicants and sponsors are submitting for reconsideration following an initial rejection of their proposed names, include the statement "**REQUEST FOR RECONSIDERATION OF PROPRIETARY NAME**" in bold, capital letters on the first page of the submission.

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

- Proposed first choice proprietary name
- Application number (BLA/NDA/ANDA/IND)
- Applicant or sponsor contact information including the company name, name and title of the contact person, address, phone number, fax number, and e-mail address
- Identification of the submission as a Request for Proprietary Name Review, Request for Reconsideration of Proprietary Name, or Amendment to a Request for Proprietary Name Review.[17]
- A list of contents in the submission

B. Proposed Proprietary Name

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

1. Primary and Alternate Proprietary Name

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

2. Intended Pronunciation of the Proposed Proprietary Name

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

[17] 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.

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

3. Derivation of Proprietary Name

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

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

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

5. Pharmacologic/Therapeutic Category

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

C. Additional Information about the Product

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

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

a. Proposed Labeling

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

b. Container Labels and Labeling

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

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

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

- If critical information, such as the drug name and concentration, is not displayed prominently or is masked by more prominent but less critical information, these factors could contribute to confusion and possible medication errors.

- If product names are obscured by a logo or are illegible because of the font or color of the text, these factors could lead to name confusion or product selection errors.

- The similar appearance of labels or labeling among different drugs or different dosage strengths of drugs could contribute to selection of an incorrect drug or product strength where product names are similar.

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

2. Submission for a Product Without Proposed Labeling

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

a. Established Name

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

b. Prescription Status

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

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

c. Dosage Form(s)

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

d. Product Strength(s)

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

e. Proposed Indication(s) for Use

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

f. Route(s) of Administration

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

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

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

h. Dosing in Specific Populations

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

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

i. Instructions for Use

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

j. Storage Requirement

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

k. How Supplied and Packaging Configuration

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

D. Information about Product Dispensing and Delivery

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

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

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

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.

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*

- eCTD Backbone File Specification for Module 1
- FDA eCTD Table of Contents Headings and Hierarchy

Applicants and sponsors are encouraged to use the Electronic Submissions Gateway (ESG) to submit regulatory information. For information on the use of the ESG, refer to http://www.fda.gov/esg/.

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."[18] Types of errors include diagnostic, treatment, preventive, and other (such as failure of communication, equipment, or system).[19]

[18] IOM, *To Err is Human.* Chapter 1, p. 1.

[19] 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.

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

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

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

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

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

Proprietary name: The trademark, trade name, or brand name.

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

[21] IOM, *Preventing Medication Errors*, Chapter 2, p. 67.