Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis, Danielle Harris at 301-796-4590, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

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)

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Drug Safety

Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products

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Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. INTRODUCTION

FDA is issuing this guidance to help sponsors of human nonprescription drug products develop **proprietary names**[2] for those products**.** This guidance describes best practices to help minimize proprietary name-related **medication errors** and otherwise avoid adoption of proprietary names that contribute to violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations. It also describes the framework FDA uses in evaluating proposed proprietary names that is available to sponsors to use for nonprescription drug products before a product bearing that proprietary name is marketed. This guidance does not address the designation of **established names** or **proper names**.

This guidance applies to all human nonprescription drug products, including those approved under a new drug application (NDA), abbreviated new drug application (ANDA)[3], or biologics license application (BLA)[4], and those that can be marketed without approved applications in accordance with requirements for nonprescription drugs under section 505G of the FD&C Act (21 U.S.C. 355h) (often referred to as over-the-counter (OTC) monograph drugs).[5] In this

[1] This guidance was prepared by the Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis in the Center for Drug Evaluation and Research (CDER), and the Advertising and Promotional Labeling Branch in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

[2] Terms that appear in bold type upon first use are described in the Glossary, as they are used in this guidance.

[3] With regard to NDAs and ANDAs, see section 505(b) and (j) of the FD&C Act (21 U.S.C. 355(b) and (j)).

[4] See section 351 of the Public Health Service Act (42 U.S.C. 262).

[5] Under section 505G, to be legally marketed without a new drug application approved under section 505, a nonprescription drug product must meet requirements that include conformity with applicable conditions for nonprescription use for the drug or class of drugs (such as those described in section 505G(a)(1)-(3) or established by order under section 505G(b)), as well as conformity with the general requirements for nonprescription drugs, which include labeling requirements under the Act and regulations.

guidance, all such products are jointly referred to as *products*, and persons responsible for developing the products are referred to as *sponsors*.

A separate guidance is available describing best practices in developing proprietary names for human prescription drug products.[6]

This guidance recommends best practices for sponsors considering proprietary names for nonprescription drugs and is intended to provide sponsors clarity and transparency with respect to the factors and framework FDA uses to evaluate proposed proprietary names for nonprescription drugs that are subject to premarket review. Use of the best practice recommendations and other assessment tools addressed in this guidance is not mandatory, and their application does not dictate specific outcomes. Assessments of a proprietary name are necessarily fact-specific and thus, where FDA makes a determination about the acceptance of a proprietary name for a nonprescription drug as part of the new drug approval process, it does so on a case-by-case basis, considering the totality of the information.

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

II. BACKGROUND

Selecting a proprietary name is a critical element in drug product design and development because **end users** may rely, in part or in whole, on the proprietary name to identify which product, among thousands of available products, is intended for or used by a particular person. Nonprescription drug product proprietary names are used by consumers, patients, caregivers, physicians and other health care professionals as primary product identifiers. Having a proprietary name that facilitates accurate identification of a nonprescription drug product by these end users is critical for its safe and effective use. For example, if end users cannot easily identify a nonprescription product or distinguish a proprietary name from other drug names that are similar phonetically (sound-alike names) or in their spelling or orthographic appearance (look-alike names), or if the drug name is otherwise confusing or misleading, the end user might select or receive the wrong product or it might not be possible to correctly identify the product used. Using best practices for selecting a proprietary name for a nonprescription drug helps minimize these hazards, which in turn both promotes public health and helps to ensure that the product conforms to legal requirements under the FD&C Act.

To inform their risk assessment of a proposed nonprescription product proprietary name, sponsors should consider how their nonprescription product will be used by consumers, patients, caregivers, physicians and other health care professionals.

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[6] See the FDA guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products* for design practices to help minimize errors with prescription proprietary names. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page, available at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Commonly, nonprescription products are selected, purchased, and used by consumers without the involvement of a health care professional. In cases where nonprescription products are recommended or prescribed by health care professionals, this is commonly done using the proprietary name.[7,8] Nonprescription products are also used in a variety of health care settings, including hospitals, emergency departments, and long term-care facilities, and their proprietary names are used during prescribing, ordering, transcribing, dispensing, administration, or medication reconciliation processes. Some nonprescription medication-use processes, for example, transcribing and medication reconciliation, involve the use of a nonprescription product proprietary name without referring to the **principal display panel (PDP)** or **drug facts labeling (DFL)**. Our post-marketing surveillance of medication error reports has found that nonprescription product proprietary names have been confused with prescription product proprietary names at various points within the medication-use process.[9,10,11,12,13,14]

Because proprietary names for nonprescription products are used by health care professionals throughout the medication-use process in a variety of health care settings, we recommend that proposed proprietary names for nonprescription products be developed and evaluated using principles that are like those used for prescription product proprietary names to help ensure that the proposed proprietary name is not subject to confusion by health care professionals. Furthermore, because proprietary names for nonprescription products are also used by consumers without the involvement of a health care professional, FDA recommends additional best practices (described in more detail below) for the development and evaluation of proposed nonprescription product proprietary names to help ensure that nonprescription product proprietary names are also not subject to confusion by consumers, and do not otherwise contribute to violations of applicable legal requirements.

Proprietary names are used in a product's **label** and **labeling**, including promotional labeling. A drug's labeling, in turn, is often a key element in FDA oversight. For example, under section 502(a) of the FD&C Act (21 U.S.C. 352(a)), a drug is misbranded if its labeling is false or misleading in any particular.[15] Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) sets forth

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[7] Tu, CM. Use of Proprietary Names by Prescribers when Prescribing Over-the-Counter (OTC) Drug Products. Therapeutic Innovation & Regulatory Science, published online April 22, 2018, available at http://journals.sagepub.com/doi/pdf/10.1177/2168479018762376

[8] Some consumers seek a prescription for their nonprescription product to qualify the purchase for reimbursement as a medical expense under flexible spending arrangements, health reimbursement arrangements, or health savings accounts.

[9] Institute for Safe Medication Practices, 2013, Safety briefs: ZERIT (stavudine) – ZYRTEC (cetirizine) mix-up, ISMP Med Saf Alert Community/Ambulatory Care, 12(9):2.

[10] Institute for Safe Medication Practices, 2005, Safety briefs: Mucinex-Mucomyst: Too close for comfort, ISMP Med Saf Alert Community/Ambulatory Care,.4(1):1-2.

[11] Institute for Safe Medication Practices, 2002, Safety briefs: Mirapex and Miralax confusion, ISMP Med Saf Alert Acute Care, 7(20):1.

[12] Institute for Safe Medication Practices, 1996, Safety briefs: More on confirmation bias. ISMP Med Saf Alert Acute Care, 1(23):1-2.

[13] Institute for Safe Medication Practices, 2014, Safety briefs: Florinef vs. Floranex, ISMP Med Saf Alert Acute Care, 19(2):2-3.

[14] Institute for Safe Medication Practices, 2008, Safety briefs: Benazepril confused with Benadryl, ISMP Med Saf Alert Community/Ambulatory Care, 7(12):2.

[15] See also 42 U.S.C. 262(j) with respect to a biological product subject to regulation under section 351 of the Public Health Service Act.

certain considerations that shall be considered when determining whether labeling is misleading. FDA regulations also address some of the ways in which the name of a drug may render its labeling misleading.[16] In addition, labeling is relevant to determining whether a drug is a new drug under section 201(p) of the FD&C Act that requires premarket approval (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

For nonprescription products that will be marketed under an NDA, ANDA, or BLA, FDA reviews proposed labeling, including any proposed proprietary name included in that labeling, on a case-by-case basis as part of the application review process. Although the Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act (BsUFA) performance goals provide for FDA to make a tentative determination of acceptance/non-acceptance of a proposed proprietary name early in the review process (in instances where the proprietary name review request is submitted as a complete submission), final acceptance of a proposed proprietary name occurs as part of the approval of the drug product.[17] To reach that conclusion, in addition to considering the safety and effectiveness data submitted to support approval, FDA considers the information and analyses about the proposed proprietary name described in this guidance, along with any additional proprietary name-related information submitted by the sponsor. In these cases, FDA's evaluation process is very similar to that which it uses to review proposed proprietary names for prescription drug products.

However, many nonprescription products and their product-specific labeling, including any proprietary name, are not reviewed and approved by FDA through product-specific applications before marketing, but instead can be legally marketed without approved applications if they conform to applicable requirements under section 505G of the FD&C Act (21 U.S.C. 355h).. Regardless of which regulatory framework governs market entry of a particular nonprescription product, we recommend that sponsors follow the best practices described in this guidance. To protect the public health, FDA supports proactive efforts to identify and avoid potential problems before the product is marketed. Also, sponsors may choose to seek FDA's views on a proposed proprietary name for an individual nonprescription drug product that they propose to market under FD&C Act section 505G, particularly where they have uncertainty about the risks presented by a proposed name.

Ultimately, regardless of whether a proprietary name has been evaluated by FDA before its use in marketing the drug product, sponsors have an ongoing obligation to ensure that each marketed product satisfies applicable requirements, such as ensuring that its labeling is not false or misleading in any particular. (See section 502(a) of the FD& C Act). If a marketed product's

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[16] See, e.g., (21 CFR 201.6(b)) (labeling for a drug containing two or more ingredients may be misleading if the name of the drug designated in that labeling includes or suggests the name of one or more but not all of the ingredients); (21 CFR 201.10(c)(3)) (labeling of a drug may be misleading if it employs a fanciful proprietary name for a drug or ingredient that implies some unique effectiveness or composition when the drug or ingredients is in fact a common substance, the limitations of which are readily recognized when it is listed by its established name); (21 CFR 201.10(c)(5)) (labeling of drug may be misleading if the proprietary name may be confused with the proprietary name or established name of a different drug or ingredient because of similarity in spelling or pronunciation).

[17] See, e.g., PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022, Items I.D.1.d and I.D.2.e. and BsUFA performance goals, see FDA's website at https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments .
See also the FDA guidance for industry Contents of a Complete Submission for the Evaluation of Proprietary Names (April 2016). https://www.fda.gov/media/72144/download

proprietary name causes or contributes to medication errors, the sponsor of that product should work expeditiously with FDA to resolve the situation. If the product does not comply with applicable requirements, and the sponsor is unwilling to address or resolve an issue voluntarily, the sponsor and/or the product may be subject to enforcement or regulatory actions.

This guidance is organized as follows:

- Section III provides recommendations for developing and evaluating **novel proprietary names** for nonprescription drug products.
- Section IV describes FDA's current thinking on the use of a proprietary name that is already associated with a marketed product(s) to introduce a new product.
- Section V provides recommendations for proprietary names for products that change from prescription to nonprescription drug status.

For each category, we believe that no single test or standard is adequate to determine whether a proposed proprietary name may contribute to errors or otherwise contribute to any violation of the FD&C Act. Rather, the current approach to proposed proprietary name evaluation uses a combination of different and complementary tests.

III. RECOMMENDATIONS FOR DEVELOPING AND EVALUATING NOVEL NONPRESCRIPTION DRUG PRODUCT PROPRIETARY NAMES

Sometimes, a sponsor proposes a novel proprietary name for its nonprescription product, for example, to introduce a new **active ingredient** or **active moiety**, a new formulation, a new indication, or for the purposes of re-branding a product undergoing a prescription-to-nonprescription switch (see section V).

We recommend that sponsors screen novel nonprescription proposed proprietary name candidates for the attributes described in section III of the guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products* [December 2020], which identifies attributes of proposed proprietary names that FDA typically finds concerning. We recommend that sponsors screen proposed proprietary name candidates for these attributes as a first step before proceeding with a full assessment of whether a name is likely to contribute to medication errors or otherwise contribute to violations of the FD&C Act. We recommend that sponsors avoid proposed nonprescription drug product proprietary names that raise concern during preliminary screening.

In addition to the recommendations for preliminary screening, FDA also recommends that sponsors consider other important attributes described below during development of a proposed proprietary name.

A. Additional Best Practices for Evaluation of Proposed Names

The following best practices are recommended to reduce the likelihood of selecting a nonprescription drug product proprietary name that contributes to medication errors or other violations of FDA-administered legal requirements, either at the time of initial product launch or in the event of future product range expansions.

1. Names That Include Reference to Product-Specific Attributes

For flexibility in future product development and naming, FDA recommends that sponsors avoid incorporating product-specific attributes, such as dosage form (e.g. "Name*tabs*") or route of administration (e.g. "Name*oral*"), as part of the proposed **root proprietary name**. It is not uncommon for product-specific attributes to change during a drug's life cycle with subsequent introductions of new dosing intervals, formulations, dosage forms, indications, and patient populations. If considering a proprietary name that includes or refers to product-specific attributes, sponsors should be mindful that future changes, such as changes in dosage form or route of administration, could render the root proprietary name inaccurate and thus unusable for future formulations.

If references to product-specific attributes are included in the root proprietary name, FDA recommends that the name be evaluated to ensure that the product-specific attribute is consistent with the terminology used in the product's labeling and does not pose risks for medication error.

2. Medical Abbreviations

Sponsors are generally discouraged from incorporating symbols, dose designations, and medical abbreviations commonly used for prescription communication in their proposed proprietary name because their inclusion could inadvertently introduce a source of error. Although we acknowledge that consumers may not be familiar with these elements, health care providers interact with nonprescription drug product proprietary names in a variety of health care settings (see section II) and thus, inclusion of these elements in a nonprescription proprietary name can contribute to confusion among these end users.

We recommend consulting The Joint Commission's "Do Not Use" list or the Institute for Safe Medication Practices (ISMP) List of Error-Prone Abbreviations, Symbols, and Dose Designations when considering the risk that a proposed proprietary name incorporating an abbreviation, symbol, or dose designation will be subject to misinterpretation.[18,19]

When evaluating a proposed proprietary name that contains an element that is also an abbreviation, symbol, or dose designation, FDA recommends considering other factors such as placement and presentation that may influence interpretation of the element to make sure the way it is presented in the name is not error-prone. As an example, "po" has been used historically as an abbreviation for oral route of administration in a medication order, typically appearing after the drug name. Therefore, while the inclusion of letters "po" in the beginning or within the root proprietary name (e.g., Poname or Napome) is unlikely to be misconstrued as a medical abbreviation, and thus would not be expected to pose a risk for medication errors, if "po" is used in the ending of the root proprietary name or as a **modifier** (e.g., Namepo or Name PO), this would increase the likelihood of "po" being misconstrued as an abbreviation for the oral route of administration and thus create confusion if this is not the intended meaning.

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[18] The Joint Commission's Official "Do Not Use" List of Abbreviations, 2004, available at: http://www.jointcommission.org/assets/1/18/Official_Do_Not_Use_List_6_111.PDF.

[19] Institute for Safe Medication Practices, 2010, List of Error-Prone Abbreviations, Symbols, and Dose Designations, Horsham (PA), available at: http://www.ismp.org/tools/errorproneabbreviations.pdf.

3. Proprietary Names of Drug Products Marketed Outside of the United States

Medication errors resulting in dispensing and administering the wrong drug can occur when a proprietary name for a product marketed in the United States is identical, or nearly identical in spelling and pronunciation, to the proprietary name of a foreign product containing an entirely different active ingredient marketed only in a foreign country.[20] For this reason, as a best practice, FDA recommends against proposing a proprietary name for a nonprescription product that is identical or nearly identical to the proprietary name of a marketed foreign product that contains an entirely different active ingredient, even if the proposed nonprescription product will be marketed only in the United States (and the foreign product is not marketed in the United States).

4. Incorporation of the Sponsor's Name

FDA recommends that sponsors avoid proposed proprietary names that incorporate the sponsor's name, or some part of the sponsor's name, across multiple products (e.g., "ABCName1," "ABCName2," "ABCName3"). This practice results in creating multiple similar proprietary names, increasing the risk of confusion among the products.

5. Modifiers as Components of a Nonprescription Proprietary Name

Some proprietary names are constructed of a root proprietary name modified by added words or components, which are referred to as modifiers**.** The modifier portion of a proprietary name generally consists of one or more letters, symbols, numbers, and/or words, and appears at the beginning or end of the root proprietary name, typically set off by a space or hyphen. Sponsors frequently propose a shared root proprietary name with various modifiers to distinguish among multiple products that contain at least one shared active ingredient or active moiety (see section IV).

Modifiers are sometimes used to convey distinguishing characteristics of the proposed nonprescription product: e.g., the symptom(s) it is intended to treat ("Name Allergy"), or the intended population ("Children's Drugname"), or frequency of administration ("Drugname 12Hour"), or formulation ("Extra Strength Drugname"). FDA recommends that the proposed modifier be evaluated to ensure that it is consistent with the characteristics of the proposed product and that it is not otherwise prone to medication error. FDA also recommends applying considerations discussed in section IV.C of guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products*.

To reduce the risk of medication errors associated with the use of modifiers in proprietary names, FDA encourages sponsors who choose to use modifiers to select, whenever possible, an existing modifier with an established meaning that has not been a source of confusion. See Appendix A for examples of modifiers which, when intended to express the accompanying meaning, have not been a source of confusion. When novel modifiers are used, sponsors are encouraged to test consumer and health care professional comprehension of the modifier to determine if the modifier is prone to misinterpretation by the end users. Such testing could include name simulation studies or other means.

[20] Institute for Safe Medication Practices, 2005, Safety briefs: Same name, different drug, ISMP Med Saf Alert Acute Care, 10(1):2.

B. Recommended Methods for Evaluating Risks for Medication Error Posed by Similarity of a Proposed Proprietary Name to Other Names

Where FDA has the opportunity to review a nonprescription product's proposed proprietary name as part of a marketing application, a primary focus of FDA's review of the proposed proprietary name is avoiding end user error. When evaluating a proposed proprietary name, FDA considers many potential sources of error, including phonetic, spelling, and orthographic similarities, as well as other sources of error identified elsewhere in this guidance.

Specific methods that FDA uses to evaluate proposed proprietary names, as well as methods that FDA recommends sponsors use for evaluation of proposed proprietary names, are described below. The descriptions include methods for identifying existing proprietary names or established names that could be confused with the sponsor's proposed name, as well as methods for assessing the likelihood and potential effects of name-related medication errors. When a proprietary name is submitted as part of an application, if a sponsor includes detailed study report(s) providing data from its own safety assessment(s) and shows that these data were generated using a methodology that is generally consistent with that described in this guidance, FDA intends to use these data to help evaluate the risk that the proposed proprietary name would contribute to medication errors. Sponsors are encouraged to conduct each of the types of assessments described below, but FDA considers what is submitted on its individual merits, regardless of whether it includes every type of testing described below.[21]

Furthermore, because nonprescription drug products are often marketed alongside cosmetics and other self-care products, we recommend that sponsors that conduct such assessments also consider the risk that the proposed nonprescription product proprietary name will be confused with marketed cosmetics or other self-care products.

1. Name Simulation Studies

Name simulation studies conducted by FDA test how health care professionals employed by FDA respond to the proposed names.[22] The studies we carry out are limited in scope because they involve only FDA staff. Although the sample size in FDA's simulation studies is small, these studies can provide important qualitative data that can be used to identify the potential vulnerability of a proposed name to be misinterpreted. The likelihood of observing an error in a small study is low, so that when an error is observed in a small study, this suggests that there will be errors in actual use. However, small studies may not be sufficiently sensitive to reliably identify all risks associated with a proposed proprietary name; the absence of observed errors in small studies is not conclusive evidence that a proposed name will not be confused with another

[21] Because sponsors do not have access to non-public information on pending proposed proprietary drug names, when considering a proprietary name in the context of a premarket application for a new drug, FDA generally intends to use the methods described in this guidance to generate data to supplement any safety assessments provided by sponsors and evaluate the proposed proprietary name for its potential to be confused with non-public pending proposed proprietary names that have been submitted to FDA.

[22] See the FDA guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products* for design practices to help minimize errors with prescription proprietary names. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page, available at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

drug product's proprietary name. For these reasons, FDA believes it would be useful for sponsors to conduct more comprehensive simulation studies.

Generally, name simulation studies test how subjects respond to a proposed proprietary name by asking subjects to use the name in conditions that simulate the real world. The more closely and fully the simulation approximates real-world use conditions, the more generalizable the results of the simulation testing. Name simulation tasks should reflect the full range and variety of tasks involved in the use of nonprescription drug products. Nonprescription products are often selected, purchased, and used by consumers without the oversight of a health care professional. Additionally, as noted in section II above, nonprescription products may be prescribed, ordered, transcribed, dispensed, or administered by health care professionals using a proprietary name in a variety of health care settings.[23] Therefore, it is important to evaluate whether all end users, including consumers and health care professionals, can interpret both written and oral communications of the proposed proprietary name. Thus, sponsors should design name simulation studies for nonprescription product proprietary names to test how consumers and health care professionals respond to the proposed name. FDA recommends that sponsors that conduct such simulation studies consider the study design principles provided in Appendix C of guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products*.

2. Computational Method To Identify Names With Potential Orthographic, Spelling, and Phonetic Similarities

FDA evaluates the orthographic and phonetic similarity of a proposed proprietary name to other names by using the Phonetic Orthographic Computer Analysis (POCA)[24] software. See section VI.C and VI.D of guidance for industry: *Best Practices in Developing Proprietary Names for Human Prescription Drug Products* for a description of the methods FDA uses, and recommends sponsors to use, to evaluate proposed names using the POCA software. If a sponsor includes data from its own POCA evaluation as part of a proposed proprietary name submission, FDA will use it to help evaluate the proposed proprietary name, provided that the methodology employed to generate the data is generally consistent with the factors outlined in the aforementioned Guidance.

C. Further Best Practices for Review, Including for Misbranding and Other Legal Concerns

Although this guidance focuses primarily on aspects of proprietary names that can contribute to medication error, it is a best practice to avoid using a proprietary name that could contribute to any violation of the FD&C Act.

For example, among other things, the FD&C Act provides that a drug is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For instance, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or

[23] Tu, CM, Use of Proprietary Names by Prescribers When Prescribing Over-the-Counter (OTC) Drug Products, *Therapeutic Innovation & Regulatory Science*, published online April 22, 2018, Available at: http://journals.sagepub.com/doi/pdf/10.1177/2168479018762376)

[24] On February 17, 2009 (74 FR 7450), FDA announced the availability of the source code and supporting technical documentation for POCA software program royalty-free to the public.

composition when it is actually a common substance, the limitations of which are readily recognized when the product is listed by its established name (see 21 CFR 201.10(c)(3)). As another example, a drug is a new drug if it is not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in its labeling (21 U.S.C. 321(p)), and it is prohibited to introduce a new drug into interstate commerce without an approved application (21 U.S.C. 331(d) and 355(a)). If the proprietary name of a drug suggests that it be used under conditions for which it is not GRASE and for which it does not have an approved new drug application, distributing that drug with labeling bearing that proprietary name would violate the FD&C Act.

IV. RECOMMENDATIONS PERTAINING TO THE USE OF A PROPRIETARY NAME ALREADY ASSOCIATED WITH MARKETED PRODUCT(S)

A. Brand Name Extension

In this guidance, FDA uses the term **brand name extension** to refer to a naming strategy that uses a proprietary name that is already associated with one or more marketed drug products, with or without a modifier, for a product that *does not share any active ingredient(s) or active moiety(ies)* with the marketed product(s). Two examples of what FDA considers as brand name extension are:

1. The proprietary name, "Drugname", is already associated with a marketed product that contains a specific active ingredient or active moiety and the sponsor uses the same proprietary name "Drugname", with or without a modifier, to introduce a new product that does not contain the same active ingredient or active moiety.
2. A sponsor uses a portion of the proprietary name already associated with a marketed drug product (e.g., the use of a shared **prefix** letter string with a modified **suffix** letter string, whereby the prefix letter string evokes the proprietary name already associated with a marketed product), with or without a modifier, to introduce a new product that does not contain the same active ingredient or active moiety.

Considering the many reports of confusion caused by brand name extension, FDA advises against using brand name extension to introduce a new nonprescription drug product. Consumers and health care professionals familiar with an existing nonprescription product, in some cases, equate that nonprescription product's proprietary name with the product's active ingredients (or active moieties) or uses.

The use of the same proprietary name, or a portion of the same proprietary name, for products that do not share at least one active ingredient (or active moiety) with the original marketed product has been reported to cause confusion among consumers or health care professionals who

are familiar with the root proprietary name.[25,26,27,28,29] The types of medication errors that have resulted from brand name extension confusion include the use of the wrong product, the use of a product for the wrong indication, the administration of an unnecessary or contraindicated active ingredient, and the use of a product in the wrong patient population, which in some cases has led to **serious adverse events** requiring hospitalization.[30,31,32,33] In addition, familiarity with the product that originated the root proprietary name increases the risk that a consumer would not recognize that a nonprescription product sharing that proprietary name has a different use, dose, or safety profile than that of the original marketed product, as **confirmation bias** related to the proprietary name can make consumers less likely to focus on other aspects of the product label or labeling that would differentiate the products.

B. Family Branding (Family Trade Names)

In this guidance, FDA uses the term *family branding* to refer to a naming strategy involving the use of the same root proprietary name to identify multiple products that *share at least one active ingredient (or active moiety) in common with one another*. In this approach, the new product shares a root proprietary name with the original marketed product but adds a distinguishing suffix or modifier to distinguish the new product from the original marketed product. This naming strategy results in the use of **family trade names**. For example, the products marketed under the names, Mucinex, Mucinex DM, and Mucinex D, use a family branding strategy to market nonprescription drug products containing guaifenesin, utilizing the modifiers "DM" and "D", to convey the additions of dextromethorphan and the decongestant pseudoephedrine to the formulation, respectively.

Family trade names create a risk of medication errors if their modifiers do not adequately differentiate the products. FDA recommends that sponsors consider the questions listed below to assess the risks of each proposed use of a family trade name in the proprietary name for a nonprescription drug product. These are considerations FDA applies, on a case-by-case basis, when it evaluates a proposed use of a family trade name for a nonprescription product.

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[25] Institute for Safe Medication Practices, 2014, Safety briefs: Another example of brand-name extension, ISMP Med Saf Alert Community/Ambulatory Care, 13(7):2-3.
[26] Institute for Safe Medication Practices, 2013, Safety briefs: Simply Saline simply isn't, ISMP Med Saf Alert Community/Ambulatory Care, 12(7):2-3.
[27] Institute for Safe Medication Practices, 2013, Allegra: Who knew it was also diphenhydrAMINE?, ISMP Med Saf Alert Community/Ambulatory Care, 12(4):4.
[28] Institute for Safe Medication Practices, 2009, Safety briefs: New brand-name extensions, ISMP Med Saf Alert Community/Ambulatory Care, 8(11):2-3.
[29] Institute for Safe Medication Practices, 2016, Safety Briefs: OTC's with similar names but totally different ingredients, ISMP Med Saf Alert Community/Ambulatory Care, 15(11):2-3.
[30] Institute for Safe Medication Practices, 2011, Safety briefs: Triaminic brand name extension could be dangerous to kids, ISMP Med Saf Alert Acute Care, 16(6):1-2.
[31] Institute for Safe Medication Practices, 2004, Safety Briefs: Cautions: Dulcolax brand name extensions, ISMP Med Saf Alert Acute Care, 9(7):1-2.
[32] FDA Drug Safety Communication: "Product Confusion with Maalox Total Relief and Maalox Liquid Products." Available at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm199476.htm . Accessed 4/15/19.
[33] Institute for Safe Medication Practices, 2010, Maalox Total Relief isn't the same great Maalox, ISMP Med Saf Alert Acute Care, 15(4):1-4.

Affirmative answers generally indicate lower risk associated with the family branding naming strategy.

- Does the proposed product share at least one active ingredient or active moiety with the first product marketed under the same root proprietary name?
- Are there no known issues of name confusion involving other marketed products using the same family trade name (see section C below)?
- Does the proposed modifier(s) adequately differentiate the proposed product from other members of the same family brand (see section III.A.5)?
- Do the results from name simulation studies, if conducted, support that the proposed name is not vulnerable to confusion with similar names (see section III.B.1)?
- Are the products within the family brand well-differentiated by other aspects of labeling (e.g., carton, container, DFL)? For example:
  - Are differences in active ingredients (or active moieties), uses, dosage, and safety profile prominently displayed on the PDP of the carton or **container closure system** to assist in differentiation?
  - Are enhanced fonts, boxing, color, or other means used to call attention to the pertinent product differences among products within a family brand?
- Is the proposed proprietary name, including the proposed modifier(s), unlikely to contribute to other legal concerns under the FD&C Act about the product (see section III.C)?

FDA generally intends to consider any supporting data that are provided by the sponsor to describe the risks, or lack thereof, related to these points when determining the acceptability of a proposed use of a family trade name as part of the review of a premarket application.

C. Obtaining Medication Error Data for Names That Are Already Associated With Marketed Products

Case reports of medication errors related to proprietary names that are already associated with marketed products can help inform the analysis of a proposed proprietary name. FDA monitors medication error reports to identify cases of name confusion with the goal of identifying relevant information about the causes of problems and failures that lead to medication error, and the Agency applies any relevant information to the evaluation of a proposed proprietary name. FDA recommends that sponsors obtain medication error report information from their internal safety databases, publicly available FDA Adverse Event Reporting System (FAERS) data,[34] published literature, and resources available through patient safety organizations, such as ISMP.

V. RECOMMENDATIONS FOR DRUG PRODUCTS SWITCHING FROM PRESCRIPTION TO NONPRESCRIPTION USE

In some cases, a drug sponsor will submit either a supplement to an approved application or a new NDA, seeking to "switch" a drug product that has been previously approved and marketed

[34] Available at https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects.

for prescription use only, to permit marketing of a nonprescription product (see 21 CFR 310.200(b)). In such a case, the sponsor might or might not propose a proprietary name for the nonprescription product that is the same as the original prescription product proprietary name. FDA evaluates these proposals on a case-by-case basis, and generally considers the factors outlined below.

A. Full Prescription-to-Nonprescription Switch

Sometimes an application for a full switch will be approved, so that all indications, dosage forms, strengths, etc. previously approved under that application for prescription-only use will now be available without a prescription, and no prescription product covered by that application will remain in the market. In these cases, continued use of the original proprietary name for the new nonprescription product is likely to be acceptable unless the switch to nonprescription status introduces new safety or legal concerns resulting from the use of the name, consistent with the discussion in this guidance.

Alternatively, the sponsor may elect to market the product under the original proprietary name with a modifier or propose a novel proprietary name for the nonprescription product (see section III).

B. Partial Prescription-to-Nonprescription Switch

In certain cases, some of a product's indications, dosage forms, or strengths previously available only by prescription are switched to nonprescription availability though others remain available by prescription only. When this occurs, use of a proprietary name for the nonprescription product that is identical to that of the prescription product would make it difficult for end users to distinguish between the two products and could contribute to medication errors. However, it may be possible to mitigate the risk of medication error by marketing the nonprescription product under a modified proprietary name. Alternatively, the sponsor may elect to propose a novel proprietary name for the nonprescription product (see section III).

VI. CONCLUSION

In conclusion, FDA's recommendations in this guidance are intended to help sponsors avoid choosing a proprietary name that is likely to contribute to medication errors or otherwise contribute to violations of the FD&C Act. In evaluating a proposed proprietary name, FDA considers the information and analyses about the proposed proprietary name described in this guidance, along with any additional name-related information submitted by the sponsor. Assessments of a proprietary name are necessarily fact-specific and thus FDA's determinations are made on a case-by-case basis, considering the totality of the information.

GLOSSARY

The following terms are described only to assist in understanding how they are used in this guidance:

Active ingredient: An *active ingredient* is any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect. See also 21 CFR 314.3(b).

Active moiety: *Active moiety* means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance. See also 21 CFR 314.3(b).

Brand name extension: FDA uses the term *brand name extension* to refer to a naming practice that uses a *proprietary name* that is already associated with one or more marketed drug products, with or without a modifier, for a product that does not share any active ingredient(s) or active moiety(ies) with the marketed product(s).

Confirmation bias: *Confirmation bias* is the tendency to search for, interpret, favor, and recall information in a way that confirms one's preexisting beliefs or hypotheses.

Container closure system: A *container closure system* refers to the sum of **packaging** components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide added protection to the drug product. A packaging system is equivalent to a container closure system.

Drug Facts Labeling (DFL): The *drug facts labeling* refers to the title, headings, subheadings, and information required under or otherwise described in § 201.66(c). See 21 CFR 201.66(c).

End user: The term *end user* includes, but is not limited to, the consumer, the patient, patient's caregiver, the prescribing physician, nurse, pharmacist, pharmacy technician, and other individuals who are involved in routine selection, purchase, procurement, stocking, storage, prescribing, dispensing, and administration of nonprescription drug products (e.g., medication technicians).

Established name: Section 502(e)(3) of the FD&C Act (21 U.S.C. 352(e)(3)) states that:

> the term "established name," with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an **official compendium**, then the official title thereof in such compendium, or (C) if neither clause (A) or clause (B) of this subparagraph applies, then the common or usual name, if any of such drug or such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug,

> in which case the official title used in the Homeopathic Pharmacopoeia shall apply [emphasis added].

Family trade name: A *family trade name* results from a naming practice involving the use of a shared *proprietary name* to market multiple products with a shared active ingredient, using a *suffix* or *modifier,* to distinguish the products from one another. This practice is also referred to as *family branding*.

Label: As defined in section 201(k) of the FD&C Act (21 U.S.C. 321(k)), the term *label* means "a display of written, printed, or graphic matter upon the immediate container of any article." If any word, statement, or other information is required by the FD&C Act to appear on the label, it must appear on the outside container or wrapper, if there is one, or be "easily legible through the outside container or wrapper."

Labeling: As defined in section 201(m) of the FD&C 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."

Medication error: A *medication error* is any preventable event that may cause or lead to inappropriate medication use or medication-related 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, prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. (See also National Coordinating Council for Medication Error Reporting and Prevention, available at https://www.nccmerp.org/about-medication-errors, accessed on 07/20/2020.)

Modifier: A *modifier* is a portion of the proprietary name. Some proprietary drug names are constructed of a root proprietary name and added word(s) or other components that are referred to as the modifier portion of the proprietary drug name. The modifier portion of a proprietary drug name might be a letter, number, word, device name, or combination of letters, numbers, and words appearing at the beginning or end of a root proprietary name, typically set off by a space or hyphen.

Novel proprietary name: A proprietary name that has not been previously used in the United States for any marketed prescription or nonprescription human drug product.

Official compendium: The term *official compendium* is defined in section 201(j) of the FD&C Act as "the official United States Pharmacopeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them."

Packaging: A *package* or *market package* refers to the container closure system and labeling, associated components (e.g., dosing cups, droppers, spoons), and external packaging (e.g., cartons or shrink wrap). A market package is the article provided to a pharmacist or retail customer upon purchase and does not include packaging used solely for the purpose of shipping such articles.

Prefix: A *prefix* is a group of letters that appears at the beginning of the proprietary name.

Principal display panel (PDP): The term *principal display panel,* as it applies to over-the-counter drugs in package form, means the part of a *label* that is most likely to be displayed,

presented, shown, or examined under customary conditions of display for retail sale. See 21 CFR 201.60.

Proper name: For biological products, the term *proper name* means the nonproprietary name designated by FDA in the license for a biological product licensed under the PHS Act. See 21 CFR 600.3(k).

Proprietary name: The *proprietary name* of a drug product is its brand name.[35]

Root proprietary name: Some proprietary names are constructed of multiple components. When a proprietary name contains a modifier as one of the components, the non-modifier portion of the proprietary name is referred to as the *root proprietary name*. The *root proprietary name* may be shared by multiple products. An example of a *root proprietary name* for a nonprescription drug product is Advil in Advil PM.

Serious adverse event: A *serious adverse event* is defined as an event that does or has the potential to result in death, hospitalization, congenital abnormality, permanent disability, or could be life-threatening. See 21 CFR 314.80 and Section 760(a)(3) of the FD&C Act, 21 U.S.C. 379aa(a)(3).

Suffix: A *suffix* is a group of letters that appears at the end of the proprietary name.

[35] Sometimes referred to as the product's "trade name"

Appendix A: Examples of Previously Used Nonprescription Drug Modifiers and Their Commonly Understood Meanings

Modifiers	Commonly Understood Meaning
Allergy	For treatment of allergy symptoms
D	Contains a decongestant
PM	For nighttime use
DM	Contains dextromethorphan
For Men	For use only in men
For Women	For use only in women
12h	Dosed every 12 hours
24h	Dosed every 24 hours