

SOPP 8001.4: Review of Proprietary Names for CBER Regulated Products

Version # 4

Effective Date: Sept 19, 2016

I. Purpose

This SOPP describes the policies, procedures, and performance goals used in the Center for Biologics Evaluation and Research (CBER) for the review and evaluation of proposed proprietary names for biological products.

II. Scope

This SOPP applies to commercial Investigational New Drugs (INDs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologic License Applications (BLAs) and supplements to these applications. This SOPP does not apply to biologic devices.

III. Background

- A.** FDA authority to regulate proprietary names is based on statute and regulations. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 321(n) states that a drug may be misbranded if “the representations made or suggested by statement, word, design, device, or any combination thereof” are misleading. FDA Code of Federal Regulations (CFR) at 21 CFR 201.10(c) states “The labeling of a drug may be misleading by reason (among other reasons) 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. [and] ... (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.” Similarly, 21 CFR 202.1(a)(3) states that advertisements “shall not employ a fanciful proprietary name for the drug or any 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.”
- B.** Confusion over the similarity of drug names for prescription, generic, and over-the-counter (OTC) products accounts for up to one quarter of medication errors (Cohen, 2007). Errors include sound-alike and look-alike proprietary and established/proper names, abbreviations, acronyms, unclear dose designations, symbols, different formulations with the same brand or generic name, and lack of terminology standardization. Evaluation of proposed proprietary names to minimize risk of medication error is part of FDA’s strategic goal to provide safe product use through effective risk management.

IV. Definitions

- A. **APLB PNR Review Memorandum** – A review memorandum generated by the Advertising and Promotional Labeling Branch (APLB) to the product review office, summarizing the review and evaluation of a proposed proprietary name with a recommendation on the acceptability of the name and suggested letter-ready language conveying the decision to the sponsor/applicant.
- B. **Medication error** - 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. **Note:** 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.
- C. **Proprietary name** - The name that will be used by the applicant or other entity for the commercial distribution of the product. **Note:** This is most often the trade name of the product.

V. Policy

- A. The primary evaluation of proposed proprietary names is made by APLB in the Division of Case Management (DCM) in the Office of Compliance and Biologics Quality (OCBQ). APLB provides a recommendation on the proposed name to the product review office.
- B. The acceptability of a proprietary name is determined by a review process that includes analysis using the FDA Phonetic and Orthographic Computer Analysis (POCA) system to determine the potential of medication error due to similarities in sound and appearance with other products and prescreening for promotional issues (false, misleading, or fanciful names) and other naming practices that are known to contribute to medication errors, including, but not limited to: use of the same proprietary name for products containing different active ingredients; reuse of an old or discontinued product's proprietary name for a different product; two different proprietary names for the same product; use of a foreign drug proprietary name for a product with different ingredients in the United States; confusion with established or proper name, brand name extensions ("umbrella branding"); and the use of modifiers, symbols, and Roman numerals as components of a proprietary name.
- C. The three categories of acceptability are: *Acceptable*, *Acceptable at this time*, or *Unacceptable*:
 - i. ***Acceptable*** – is given to a proprietary name that has passed its evaluation at the BLA, NDA, or ANDA stage. FDA is unlikely to change its decision on the acceptability of this name prior to product approval given a normal application review period.
 - ii. ***Acceptable at this time*** – is given to a proprietary name that has passed its evaluation at the IND stage. FDA will review the proprietary name again under the BLA, to ensure that there have been no other names or considerations that have occurred in the interim that would change its decision.

- iii. **Unacceptable** – is given to a proprietary name that failed its evaluation using the above criteria. The sponsor will be asked to submit new proprietary names for evaluation.
- D. The sponsor/applicant may initially propose, at most, two proprietary names, specifying the primary name of choice. The alternative name will be evaluated only in the event the primary name is found unacceptable AND the sponsor/applicant has submitted a new and complete request that it would like the alternative name reviewed. Once the request is received, a new review clock will begin for the review of the alternative name.
- E. The product review office makes the final decision on the acceptability of the proposed proprietary name. If the product review office and APLB disagree about the acceptability of the proposed proprietary name, then a joint meeting will be held to discuss their differences.
- F. The review performance goals are 180 days for submissions received under an IND and 90 days for submissions received under a BLA/NDA/ANDA.
- G. To ensure adequate time for revision, the sponsor/applicant should be notified of the rejection of a proprietary name as soon as it has been determined. If a proprietary name is rejected, then the sponsor/applicant may request reconsideration by submitting a written rebuttal with supporting data or request a meeting (classified as a “Type C” meeting) within 60 days to discuss the initial decision. A meeting package is required as provided in *Guidance for Industry, Formal Meetings with Sponsors and Applicants for PDUFA Products*.
- H. Because proprietary name review considers the indication, ingredient(s) and product characteristics (such as route of administration, dosage form, storage conditions, etc.) of a particular product, the acceptance of a proposed proprietary name for one product does not mean that the proprietary name would be acceptable for another product. Therefore, a proposed proprietary name must be submitted for evaluation for each new product.
- I. Proprietary names cannot be reserved.
- J. A proprietary name is not “approved” separately from the approval of the product labeling (prescribing information, carton, and container labeling).
- K. Proprietary names that have been in use cannot be purchased and used for other products.
- L. A change to a proposed proprietary name under a pending BLA/NDA/ANDA should be submitted as an amendment to the application withdrawing the name. A new review clock will start for the newly proposed proprietary name, subject to the same review timelines as the original name.

VI. Responsibilities

- A. **Document Control Center (DCC)** – Receives, processes and routes the submission to the responsible product review office and RIMS, as appropriate.
- B. **Regulatory Information Management Staff (RIMS)** - Receives archival copy of IND submission and categorizes Proprietary Name Review requests (PNRs) in BIRAMS.

C. Product Review Office - Processes and routes the PNR to appropriate reviewers. Sends notification of PNR submission receipt to APLB Branch Chief. Makes the final decision on the acceptability of the proprietary name.

D. Advertising and Promotional Labeling Branch (APLB) – Determines whether the initial submission is complete. Reviews the proposed proprietary name. Prepares a labeling memorandum with the results of its review and sends to the product review office.

VII. Procedures

A. Receipt and Initial Processing of PNR Requests

1. Investigational Submissions

- a.** For paper submissions: receives, date stamps and processes the submission in accordance with DCC procedure guides. Routes the submission to RIMS and to the responsible product review office. **[DCC]**
- b.** For electronic submissions: DCC processes, loads into CBER's Electronic Document Room (EDR) and sends the load notification to RIMS and the product review office. **[DCC]**
- c.** Receives the IND submission from DCC, enters the proposed name(s) into BIRAMS, and categorizes it as a PNR request within 1 business day. **[RIMS]**
 - i.** A PNR request may have one or two names. Both names are entered into the database, noting which is primary and which is alternative. **Note:** one name is reviewed except under exceptional circumstances.
- d.** Receives the PNR request from DCC and promptly processes the submission. (Refers to any materials submitted by the sponsor regarding the proprietary name review, including responses to deficiency communications and proprietary name withdrawals.) **[RPM]**

2. Marketing Applications

- a.** Receives and processes the submission in accordance with DCC procedure guides. **[DCC]**
- b.** Routes the submission to the responsible product review office. For electronic submissions, DCC processes, loads into CBER's Electronic Document Room (EDR) and sends the load notification to the responsible product review office. **[DCC]**
- c.** Receives the PNR request from DCC and promptly processes the submission. (Refers to any materials submitted by the applicant regarding the proprietary name review, including responses to deficiency communications and proprietary name withdrawals.) **[RPM]**

- d. Enters the PNR request into RMS/BLA **[RPM]**
 - i. A PNR request may have one or two names. Both names are entered into the database, noting which is primary and which is alternative. **Note:** one name is reviewed except under exceptional circumstances.
- 3. Notify APLB Branch Chief of the existence of a PNR submission. **[RPM or designee]** The notification should include:
 - a. STN or IND number, PDUFA goal dates if applicable, product review office goal dates
 - b. a copy of the PNR submission or a link to an electronic submission
 - c. all other relevant materials/information
- 4. Acknowledges the product review office's notification and assigns a reviewer to the PNR submission. **[APLB Branch Chief]**
- 5. Promptly routes the submission to the APLB reviewer, clinical reviewer, and others, as appropriate. **[RPM or designee]**

B. Review

- 6. Performs initial review for submission completeness and notifies product review office if the submission is incomplete. **[APLB Reviewer]**
- 7. Evaluates the proposed name(s). **[APLB Reviewer]**
- 8. Consults with the review committee regarding any significant concerns with the acceptability of the proposed proprietary name and documents the review committee's response in the APLB review memorandum. **[APLB Reviewer]**
- 9. Consults with the Office of Biostatistics and Epidemiology to address any safety concerns, as necessary. **[APLB Reviewer]**
- 10. Prepares APLB's review memorandum with letter-ready language regarding the acceptability (including reasons if unacceptable) of the proposed proprietary name. **[APLB Reviewer]**
- 11. Enters the review memorandum into the appropriate database and uploads into the EDR at least 10 days prior to the PNR due date; sends notification to the review committee. **[APLB Reviewer]**
- 12. Receives APLB's review memorandum. **[RPM]**
- 13. Initiates a meeting with APLB staff to discuss disagreement or concerns regarding APLB's final recommendation, if necessary. **[RPM]**

14. Makes the final decision on the acceptability of the proprietary name. [**Committee Chair**]
15. Documents in a memo to the file the reason(s) for not accepting APLB's recommendations, if appropriate; enters memo in the appropriate database and uploads into the EDR. [**Committee Chair**]
16. Communicates CBER's decision on the proposed proprietary name to the sponsor/applicant within the specified timeframe (as early as possible, if the name is determined to be unacceptable) using language from the letter templates. [**RPM**]
 - a. The communication may be a letter, fax, secure e-mail, or teleconference with memorandum to file.
 - b. The letter or telecon memorandum must be loaded into the EDR.
17. Notifies APLB once the communication is issued to the sponsor/applicant. [**RPM**]
18. Provides APLB's review memorandum and sponsor/applicant notification to the CDER PNR coordinator for Agency reporting (after sponsor/ applicant has been notified of FDA's decision). [**APLB Reviewer**]
19. Enters the date of the communication issuance into the appropriate database which closes the milestone/stops the clock. [**RPM**]

C. Request for PNR withdrawal from Sponsor/Applicant

1. Acknowledges the withdrawal of the PNR request submission with a communication to the sponsor/applicant [**Product Office RPM**]
2. Reclassifies the submission as *Withdrawn* in the appropriate database [**Product Office RPM**]
3. Notifies APLB that the submission has been withdrawn. [**Product Office RPM**]

D. Request for Re-evaluation

1. Promptly forwards any supporting documents or arguments to the APLB Branch Chief for evaluation when a sponsor appeals an *Unacceptable* decision. [**RPM**]
 - a. The sponsor may request reconsideration by submitting a written rebuttal with supporting data or request a meeting within 60 days to discuss the initial decision.
 - b. A meeting package is required as provided in *Guidance for Industry, Formal Meetings with Sponsors and Applicants for PDUFA Products*.

VIII. Appendix – N/A

IX. References

Web links to the references below can be found in the list following the History Table (unless otherwise noted)

1. Prescription Drug User Fee Act (PDUFA)
<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>
2. Food and Drug Administration Amendments Act of 2007
<http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm>
3. National Coordinating Council for Medication Error Reporting and Prevention (no link provided)
4. Guidance for Industry – Contents of a Complete Submission for the Evaluation of Proprietary Name
<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm075068.pdf>
5. Draft Guidance for Industry – Best Practices in Developing Proprietary Names for Drugs.
www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm398997.pdf
6. Guidance for Industry, Formal Meetings With Sponsors and Applicants for PDUFA Products
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079744.pdf>
7. November 2002, the Secretary of Health and Human Services report: Bringing common sense to health care regulation: report of the Secretary's Advisory Committee on Regulatory Reform - November 21, 2002. (no link provided)
8. 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) (no link provided)
9. Cohen, Michael. 2007. *Medication Errors*. Washington, DC: American Pharmacists Association. (no link provided)

X. History

Written/Revised	Approved	Approval Date	Version Number	Comment
Lisa Stockbridge	Christopher Joneckis, PhD	Sept 11, 2016	4	Revision to Policy to remove “acceptable with concerns”
Lisa Stockbridge	Christopher Joneckis, PhD	Jan 18, 2016	3	Revisions to content pursuant to sunset of the PNR pilot
Catherine Miller	Robert Yetter, PhD	Sept 30, 2008	2	Revisions to content pursuant to FDAAA and PDUFA IV
Mary Malarkey	Robert Yetter, Ph.D.	Aug15, 2002	1	Original Document