
Manual of Standard Operating Procedures and Policies

General Information - Review

Review of CBER Regulated Product Proprietary Names

SOPP 8801.4

Version #1

Date: August 15, 2002

1. Purpose

This document describes the procedures and factors considered by the Center for Biologics Evaluation and Research (CBER) when reviewing proposed proprietary names for biological products.

This document is not applicable to biological devices.

2. Definitions

Proper Name:

The name designated in the license for use upon each package of the product [Reference 21 CFR 600.3(k)].

Established name:

The official name of a product designated under Section 508 of the Act. If such a name has not been established under this provision and the product is recognized in an official compendium, then the product title in the compendium is used. If neither exists then the common or usual name is used. Under the regulations in 21 CFR 299 The United States Adopted Names Council (USAN) is the recognized expert for the selection of nonproprietary names of drugs.

Proprietary name:

The name the applicant or other entity will use for the commercial distribution of the product. This is the name that will identify their specific product on the marketplace following approval by FDA / CBER. For example, While on the market, ACEL-IMUNE® was the registered trademark for the product Diphtheria and Tetanus Toxoid and Acellular Pertussis Vaccine Adsorbed manufactured by Lederle Laboratories.

Tradename:

A select category of proprietary names that are used to denote the name the company is doing business under. For example the name "*Nike*" with the swoop under the name is the tradename; "*AIR*", a specific shoe in their line, is the trademarked proprietary name.

3. Background

Approximately 12.5% of medication errors occur as a result of confusion of one proprietary name being mistaken for another by a health professional. Approximately 50% of reported errors are related to the labeling and/or packaging and naming of products. Medication errors pose a serious risk to public health in that they could lead to death or serious injury. FDA and the pharmaceutical industry have a responsibility to ensure that a product does not bear a proprietary name that could be confused with another proprietary name or proper name. On May 10, 1999, FDA Commissioner Jane E. Henney, M.D., released a report that 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. The Institute of Medicine's December 1999 report on medical errors recommended that FDA take measures to identify and remedy potential sound-alike, look alike drug names and confusing labels and packaging.

4. Policy

It is the policy of CBER that a proposed proprietary name will not be accepted if the name:

- suggests greater safety or efficacy than supported by clinical data;
- includes or suggests indications, dosage regimens, dosage forms or routes of administration other than those for which the product is labeled;
- has the potential to contribute to medication errors or cause confusion in the market place because the spelling or pronunciation is similar to another product on the market.
- includes or suggests an active component that is not part of the product e.g., use of a USAN stem in the stem position when the product does not have the therapeutic or pharmacological characteristic that the stem implies. However, if the USAN stem is used appropriately, is not used in the stem position, and enables differentiation between two or more potentially conflicting names, such use may be deemed appropriate.
- Is a different name for an essentially identical product for a different indication. Practitioners and patients may not understand or realize that two products with different names may be the same. In such cases, a patient may be inadvertently overdosed. Additionally, use of different names for the same product may pose problems in the collection and management of adverse drug reaction reports.

It is CBER's policy that all proposed proprietary names be reviewed prior to product approval by the CBER/OCBQ/DCM, Division Director and the Advertising and Promotional Labeling Branch (APLB), consistent with provisions contained in the Federal Food, Drug and Cosmetic Act (the Act), the applicable regulations, and the criteria established by the CDER/Office of Drug Safety (ODS).

CBER will ordinarily evaluate up to 2 proposed names. The proposed names may be submitted to the product review office any time after the end of Phase 2 of the IND or with a BLA or NDA.

Upon receipt of a consult review from the product office, APLB will issue a recommendation to the product review office regarding the acceptability of the proposed proprietary name. However, any recommendation made prior to approval is considered tentative and should be reevaluated closer to the time of licensure to ensure that no new products have entered the marketplace that could give rise to confusion because of similarity in spelling or pronunciation.

5. Responsibilities and Procedures

The Product Review Office

The following procedures are to be used by CBER staff.

- **Consultation request**
 - The request for review is received by the product office and sent to the Regulatory Project Manager (RPM). The RPM has the responsibility of drafting and forwarding a request for a consult review by APLB to the Branch Chief, APLB, in a timeframe consistent with the APLB review times subsequently indicated herein.

The consultation request should include:

- the product review office's preliminary evaluation of the acceptability of the proposed name;
 - pertinent safety information, which could be used to aid in the full evaluation of the proposed name, e.g. the proposed name may suggest or imply a high safety but the product has serious side effects; and,
 - the information identified in Appendix 1.
- **Communication with applicant**
 - The product review office will ultimately make the final decision on the acceptability of the proposed

proprietary name and communicate CBER's findings to the applicant. If the name has been tentatively agreed upon, the sponsor should be notified that the proprietary name will be reevaluated for final clearance closer to the time of market approval. If the name is rejected, a detailed explanation as to why the name was rejected should be provided to the applicant.

If the proprietary name has received tentative approval, reviewed prior to 90 days of application approval, the product review office should resubmit the name to APLB when the product is within 90 days of approval. This 90-day review is the final evaluation of a tentatively accepted proprietary name to ensure that FDA has not approved a conflicting product name in the interim. The review is to be limited to a check for conflict with currently approved proprietary names and performed within 30 days, if feasible. This will allow time for the applicant to provide final container and package labeling prior to application approval.

Advertising and Promotional Labeling Branch

Review Procedure

Upon receipt of a request for consultation, an APLB reviewer will be assigned. The APLB reviewer will review the proposed name using the applicable criteria (see Appendix 2) and submit their recommendation through the Branch Chief, APLB, and Director, DCM to the product review office within 30 days of receipt of the consultation request. If the APLB recommendation is that the name not be accepted, the review memo will include the reviewer's reasons for that finding.

Requests for Reevaluation

If the APLB review concludes that the proposed proprietary name is not acceptable, the product review office or the applicant may request a reevaluation. The reevaluation may be based in part on objections provided by staff within the product review office, additional information provided by the firm or based on the outcome of a consult review with CDER's ODS. Depending upon the complexity of the information submitted the entire reevaluation process should ordinarily be completed within 60 days of receipt of the request.

If, after reviewing the additional information, the APLB continues to find the proposed proprietary name unacceptable, APLB will, at the request of the product review office or applicant, forward the information to the Associate Director for Labeling Policy and Medical Communication (ADLPMC), OCBQ for additional reevaluation. The ADLPMC will review the APLB recommendation, review all information supplied by the firm, and consult with appropriate staff within the product office and/or Center. At the conclusion of the review, the ADLPMC together with the APLB Branch Chief and the APLB reviewer will reach a consensus on the proposal. The APLB Branch Chief will document the consensus and forward it to the product review office.

Consultation with CDER's ODS

When warranted in circumstances where agreement within the Center cannot be reached, the product review office or applicant may request that the APLB request a consult review by ODS. ODS will evaluate the proposed name using its established criteria and submit its recommendation to the APLB. If ODS's findings differ from APLB's recommendation, APLB will consult with Center staff and reassess all of the information and relay its final recommendations to the product review office.

6. Effective Date

August 15, 2002

7. Appendices

[Appendix 1: Request for Proprietary Name Review](#)

[Appendix 2: Review Criteria](#)

8. History

Written/Revised	Approved	Approval Date	Version Number	Comment
Mary Malarkey	Robert Yetter, Ph.D.	August 15, 2002	1	Original Document

Updated: August 21, 2002