SOPP 8426: Assignment of Biological and Drug Product Proper Names and Biological Suffixes

Version: 8
Effective Date: July 31, 2024

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I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff on the assignment of the core (or root) proper names for biological drug products, as well as the addition of a suffix for certain original (innovator) and biosimilar products.

II. Scope

A. This SOPP describes CBER's approach to designating the proper name for biological drug products including the suffix format applicable to certain originator biological products, related biological products, and biosimilar products previously licensed and newly licensed under section 351(a) or 351(k) of the PHS Act.

B. This SOPP does not address.

- Whole Blood, Red Blood Cells, Platelets, Cryoprecipitate, and Source Plasma. (See 21 CFR PART 640)
- Diagnostic Substances for Laboratory Tests. (See 21 CFR PART 660)

III. Background

A. CBER reviews proper names for biological products under its jurisdiction.

B. A 351(a) biological product is a stand-alone (a.k.a. innovator, original) biological product submitted under section 351(a) of the PHS Act. A 351(k) biological product is a product for which there is a previously licensed BLA (reference product) and for which the applicant demonstrates that the product is highly similar or interchangeable (i.e., same active and clinically relevant inactive ingredients).

C. For PHS Act 351(a) and 351(k) biological products, a distinguishing suffix, which is devoid of meaning and composed of four lowercase letters, may be attached to the core name with a hyphen. The addition of a suffix to certain products is intended to enhance biological product pharmacovigilance, ensure safe use, and advance appropriate practices and perceptions.[1]

D. CBER assigns a descriptive proper name during the BLA review period. As a guide for assigning a proper name, CBER may use certain nomenclature conventions (e.g., United States Adopted Names (USAN), International Nonproprietary Naming (INN)). An applicant may propose a proper name in their BLA submission for CBER to evaluate for assignment of the proper name.

IV. Definitions

A. Biosimilar Product: A biological product submitted in a 351(k) application that has been shown to be highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product (See section 351(i)(2) of the PHS Act).

[1] https://www.fda.gov/media/93218/download

B. Core name: The proper name shared among an original biological product, Reference Product, biosimilar product, or interchangeable product, excluding the distinguishing suffix.

C. Original (originator) Biological Product: A biological product submitted in a BLA under section 351(a) of the PHS Act (i.e., a stand-alone BLA).

D. Proper name: The name designated in the application for use upon each package of the product (see 21 CFR 600.3(k)). Note: The proper name also may be referred to as the established or nonproprietary name.

E. Proprietary name: The exclusive name of a drug or biological product owned by a company under trademark law regardless of registration status with the Patent and Trademark Office. Note: The proprietary name may also be referred to as the trade name, brand name, or product name.

F. Product Title: A product title is the listing name of an item being sold. For drug and biological products, the product title is defined as those elements required in 21 CFR 201.57(a)(2) (i.e., drug names (proprietary and proper), dosage form, route of administration, and, if applicable, controlled substance symbol) (see 21 CFR §610.62 for product title format on container and package labels and *Guidance for Industry: Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products – Content and Format* for format of the product title in the prescribing information*).*

G. Reference Product: The original biological product licensed under section 351(a) of the PHS Act against which a biological product is evaluated in a 351(k) application.

H. Suffix: Four lowercase letters devoid of meaning, which are added to the core name to distinguish between biologics and biosimilars.

I. USAN: The United States Adopted Names Council - a private organization sponsored by the American Medical Association, and the American Pharmaceutical Association, that has engaged in the assignment of certain drug names since 1964. The council negotiates with manufacturing firms in the selection of nonproprietary names for drugs.

V. Policy

A. The designation of the core proper name is the responsibility of the product review office.

B. The addition of a suffix to the core proper name is recommended for some biological products licensed under section 351(a) or 351(k) of the PHS Act. Autologous products and childhood vaccines are exempt from the suffix requirements. In both cases, robust identification practices exist to ensure safe dispensing and optimal pharmacovigilance.

C. Applicants may voluntarily submit up to ten proposed suffixes with their BLA. The Advertising and Promotional Labeling Branch (APLB) will review proposed suffixes. The designation of the suffix is determined by APLB, in consultation with the FDA Biological Product Naming Workgroup, as needed.

D. The formal assignment of the proper name (core-suffix) will occur before product approval.

E. The proper name format is core-suffix enclosed in parentheses, e.g., (purebiologic-xtya). There are no parentheses within the name itself. Commas, rather than parentheses, are used to separate elements within the name. Unless part of a specific chemical entity, the only hyphen used should be that preceded by the four-letter suffix. (See *Guidance for Industry: Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products -Content and Format*.) The proper name should not include the following:

- Route of administration (ROA)
- Dosage form
- Strength or concentration
- Manufacturing process steps
- Storage conditions

Note: ROA or other product descriptors should be a case-by-case decision. For example, the ROA may be included in the name for safety reasons. In those cases, the ROA should be stated last, e.g., Rotavirus Vaccine, Live, Oral.

F. The designation of a suffix does not apply to:

- In vitro reagents
- Blood donor screening tests
- Reagents used in determining donor/recipient compatibility in transfusion medicine
- ISBT 128 cord blood products

G. CBER Proper Naming Conventions - Product review offices generally follow the proper naming conventions listed below based on the product type.

1. Vaccine Products

a. Live vaccines: The word, "Live" should be a component of the proper name and should be stated at the end of the name.

b. Inactivated vaccine: The word, "Inactivated" should be removed from the proper name. This information should be part of the prescribing information provided that all vaccines containing living (attenuated) organisms contain the word "Live" in the proper name.

c. Viral vaccines: The word, “Virus” should be removed from vaccine proper names unless part of another word (e.g., Papillomavirus) or unless the disease includes the name of the virus (e.g., Respiratory Syncytial Virus Vaccine).

d. Microbial strains: Viral or bacterial strains do not have to be specified in the proper name. This information can be provided in the prescribing information.

e. Polysaccharides: The word, “polysaccharide” should be included in the vaccine proper name for those products not conjugated (e.g., Pneumococcal polysaccharide 23-valent). The word, “polysaccharide” should be omitted from those bacterial products that represent conjugate vaccines.

f. Antigenic valency: The proper name may indicate a product’s valency as a number, but it is generally not necessary to list individual serotypes; the latter will be part of the prescribing information. For certain low valency products, it may be feasible to include the serogroups/serotypes. For example, Meningococcal Groups A, B, C, W, and Y Vaccine).

g. Conjugate vaccines: In general, it is not necessary to include “Conjugate”. An exception may be necessary if an unconjugated vaccine for the same indication is also available or if there is a differential safety/effectiveness profile between vaccines for the same indication. When used, using it in a redundant manner should be avoided.

h. Production media: The production media should not be part of the proper name; this information must be included in the prescribing information.

i. Adjuvants: Aluminum-adjuvanted products should specify the name, “adsorbed” in the proprietary proper name. For vaccines formulated with other adjuvants the term “adjuvanted” should be used in the proper name to clarify that the product is formulated with adjuvant. The adjuvant must be described in the prescribing information.

j. Combination vaccines: The word “combined” should be omitted from the proper name.

k. Multiple uses of the term “vaccine” within a name: The word “vaccine” should only be used once in the proper name.

l. Diphtheria and tetanus toxoid products: The target population should not be part of the proper name; however, the target population may be indicated on the package and container labels. The regulations in 21 CFR 610.60 do not preclude indicating the target population on the container label.

m. Prophylactic vaccines: The term “vaccine” should be included in the proper name.

2. Plasma Derivatives and Recombinant Analogues

Each proper name comprises the historical, scientific name of the protein with a comma followed by its origin, for example:

- antihemophilic factor, human
- antihemophilic factor, porcine
- antihemophilic factor, recombinant
- coagulation factor IX, human
- coagulation factor IX, recombinant
- coagulation factor VIIa, recombinant
- alpha$_1$-proteinase inhibitor, human
- C1-esterase inhibitor, recombinant
- antithrombin, human

A short descriptor may be added to identify a unique attribute or a commonly used name for the product, for example:

- antihemophilic factor, recombinant, Fc Fusion Protein

- coagulation factor XIII, recombinant, A Subunit
- immune globulin intravenous, human
- immune globulin subcutaneous, human

VI. Responsibilities

A. Office of Compliance and Biologics Quality (OCBQ)/Division of Case Management (DCM)/Advertising and Promotional Labeling Branch (APLB) Chief – Reviews proposed suffix(es) and designates one. If an acceptable suffix is not submitted by the applicant, a prescreened randomly generated suffix will be assigned.

B. Product Office Division Director or Designee – Evaluates proper name recommendations and makes the final determination on novel proper names.

C. Chair – Provides guidance and direction to the applicant on the assignment of the proper name (usually pre-BLA/NDA). Upon application receipt, collaborates with staff, evaluates proper name recommendations, and assists in final determination of novel proper names.

D. Regulatory Project Manager (RPM) or designee – Upon application receipt, collaborates with the review staff to determine acceptability. Communicates acceptable proper name to RIB.

E. Office of Regulatory Operations (ORO)/Division of Informatics (DI)/Regulatory Information Branch (RIB) – Enters all new proper names and suffixes into the appropriate system(s) following notification from the RPM. Flags and resolves errors with data entry regarding the proposed name and existing names with the review office.

VII. Procedures

A. Proper Name Assignment (all products)

1. Provides guidance and recommendations to the applicant on the proposed proper name or other communications before submission receipt. **[RPM/Chair]**

2. Notifies RIB of the proposed proper name. **[RPM]**

3. Using *T833.01: Characterization of Proper Names in RMS-BLA*, ensures that RIB has needed attributes for categorizing the proper name within the regulatory system. **[RPM/Chair]**

4. Enters the proper name and information provided by the RPM on T833.01 into the appropriate regulatory system(s). **[RIB]**

5. Reviews the proper name and collaborates with review committee and the product Office Division Director, as appropriate, on proper name acceptability. Obtains concurrence or correction on new proper name. **[Chair]**

    - If the proper name is not assigned by USAN or not codified in the Code of Federal Regulations (CFR), assigns the proper name as outlined in the policy section. **[Product Office]**

6. Notifies RPM on the acceptability or assignment of the proper name. **[Chair]**

B. Suffix Assignment (applicable biological products)

1. Submits up to 10 proposed suffixes, in the order of preference, at the time of BLA submission. **[Applicant]**

2. Reviews the submission for inclusion of suffixes **[RPM]**

    a. If an applicant has not included a list of suffixes for review, sends an email notification requesting the submission of suffixes using the template *T910.18: Email Template - Request for Proposed Suffixes*. **[RPM]**

3. Notifies APLB Chief of suffixes receipt **[RPM]**

4. If the applicant does not submit proposed suffixes, assigns one from prescreened, randomly generated list. **[APLB Chief]**

5. Provides suffix review memo with decision in letter-ready language for inclusion in communication to applicant. **[APLB Chief]**

6. Notifies the applicant of the acceptability of the proposed suffix, using the letter-ready language provided in the suffix review memo. **[RPM]**

7. Requests RIB to update the proper name (core-suffix) in the appropriate regulatory system(s). **[RPM]**

8. Enters proper name (core-suffix) and notifies the review office (RPM) when data entry is complete. **[RIB]**

VIII. Appendix

Not Applicable

IX. References

A. References below are CBER Internal:

1. LTR-BLAPND-01 Letter Template for Proposed Suffix(es)
2. T 910.18: Email Template - Request for Proposed Suffixes
3. T833.01: Characterization of Proper Names in RMS-BLA

B. References below may be found on the Internet:

1. Guidance for Industry: Nonproprietary Naming of Biological Products
2. Draft: Guidance to Industry: Nonproprietary Naming of Biological Products: Update
3. Guidance for Industry: Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products -Content and Format
4. United Stated Adopted Names (USAN)
5. International Nonproprietary Names (INN)

X. History

Written/ Revised	Approved	Approval Date	Version Number	Comment
Stockbridge /Valencia	Sonday Kelly, MS, PMP, RAC Director, DROP/ORO	July 31, 2024	8	Removed unnecessary examples that are available in the CFR; Removed unclear information on the role of USAN in the assignment of proper name; Reorganized content; Updated definitions per RMCC approved definitions; Updated scope language on suffix assignment to reflect NP guidance.
Kendra Moran	Katie Rivers Chief, RABOB/DROP/ORO	August 3, 2023	7	Clarifies Proper Name data entry procedures
Martha Monser	N/A	February 27, 2023	6	Technical update due to 2023 CBER reorganization
Martha Monser	N/A	February 27, 2022	5	Technical update due to 2022 CBER reorganization
Martha Monser	N/A	December 11, 2020	4	Technical Update to remove references to “database” and to use “system”
Martha Monser	N/A	March 31, 2020	3	Technical Update to Current format/font
Iliana Valencia	Chris Joneckis, Ph.D.	March 31, 2019	2	Major revision to include procedure for the FDA-designated suffix
Carla Vincent	Chris Joneckis, Ph.D.	Jan 18, 2016	1	First issuance of this SOPP