Process for Reviewing Nonproprietary Name Suffix for Biological Products

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Learning Objectives

- Understand FDA's naming convention for nonproprietary name of biological products
- Understand the reasons for FDA's naming convention for nonproprietary name of biological products
- Understand how FDA evaluates nonproprietary name suffix for biological products

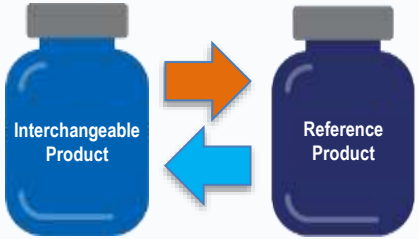
Some Basic Concepts

Reference Product

A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared

Biosimilar Product

A biosimilar is a biological product that is **highly similar and has no clinically meaningful differences** from an existing FDA-approved reference product



Interchangeable Product

An interchangeable is a biosimilar product that can be substituted for the reference product without the intervention of the prescribing health care provider

Safety and Monitoring

- All drugs have risks and benefits. Biosimilars can have side effects, which are expected to be the same as those of the reference product.
- As part of its review, FDA assesses the manufacturing process and the manufacturer's strategy to control within-product variations for all biologicals.
- These control strategies are put in place to help ensure that manufacturers produce biological products with consistent clinical performance.
- **Robust post-marketing safety monitoring** is also an important component in ensuring the safety and effectiveness of all biological products, including biosimilar products.

Naming for biological products

- *Proprietary name*: generally trademarked and registered for private use.

- *Proper name* (aka nonproprietary name): reflects certain scientific characteristics of the product. FDA designates proper names for use upon each package of the biological product.

- FDA developed a *naming convention* to help ensure safe use and pharmacovigilance for biological products.

Biological Product Naming Development

- In August 2015, FDA published the draft guidance *Nonproprietary Naming of Biological Products*, which was finalized in January 2017. Most recently, FDA published a draft update guidance in March 2019. The guidance describes FDA's current thinking on the nonproprietary naming convention for biological products licensed under the Public Health Service Act (PHS Act).

- Nonproprietary names (i.e. proper names) for biological products should include **a core name attached by a hyphen to an FDA-designated suffix that is devoid of meaning.**

- **A unique suffix should be designated for each originator biological product, related biological product and biosimilar product**.

Application of Naming Convention

Core name-suffix

- infliximab-dyyb
- epoetin alfa-epbx
- trastuzumab and hyaluronidase-oysk
- fam-trastuzumab deruxtecan-nxki

Application of Naming Convention

- Core name-suffix
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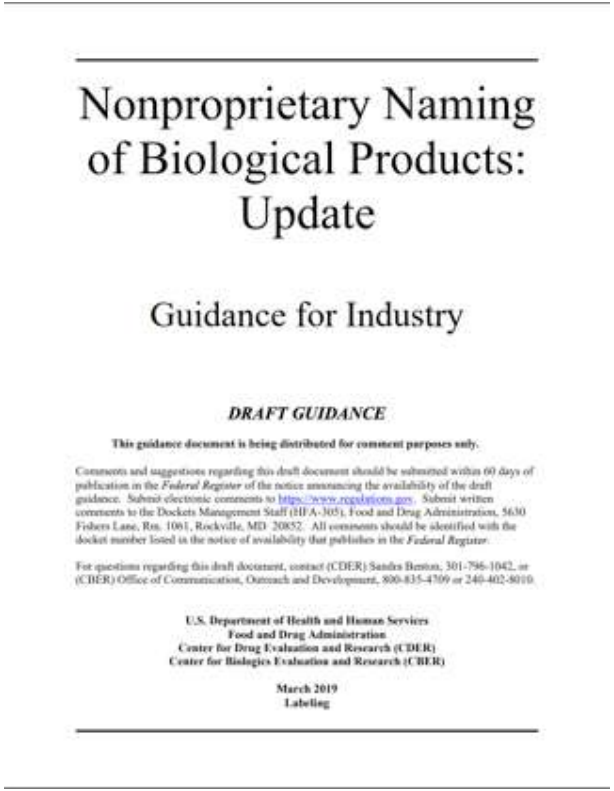
Update to the Naming Guidance



Nonproprietary Naming of Biological Products: Update

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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

For questions regarding this draft document, contact (CDER) Sandra Benton, 301-796-1042, 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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Labeling

Objectives of the naming convention described in the 2017 final guidance can be accomplished without revising the nonproprietary names of:

(1) biological products licensed under section 351 of the PHS Act without an FDA-designated suffix in their proper names or

(2) transition biological products

- For each interchangeable product, FDA intends to designate a proper name that is a combination of the core name and a unique distinguishing suffix

Naming Convention: Update, March 2019

Applying a suffix to **already licensed** products is not necessary to achieve the goals of safe use and pharmacovigilance.

- –avoids the undue burden associated with retrospective application of the naming convention
- –avoids risk of adverse patient safety issues, patient/ provider confusion, drug shortages, and supply chain disruption associated with post-approval name change.

Objectives Of The Naming Convention

Transparency:

- Facilitates identification of products for safe use and pharmacovigilance
- Facilitates prescribing and dispensing of the intended product
- Patients and providers want to know what the patient received

Trust:

- Provides FDA and others with another critical tool to perform product-specific pharmacovigilance in all settings of care

Uptake:

- Enhanced prescriber and public confidence may facilitate market uptake

Naming Convention: Safe Use of Biological Products

- The ability to **clearly identify** biological products can help ensure safe use and facilitate accurate prescribing and dispensing of biological products.

- In **clinical practice**, the ability to distinguish among originator biological products, related biological products, and biosimilars is important.
  - A biosimilar product may be licensed for fewer than all conditions of use or routes of administration for which its reference product is licensed.
  - Related biological products may be licensed for different conditions of use or routes of administration than those approved for the originator product.
  - Biosimilar products and related biological products may be packaged in different delivery systems (e.g., pre-filled syringes instead of a vial) than those approved for the originator product.

Naming Convention: Biological Product Pharmacovigilance

Pharmacovigilance systems, both active and passive, vary in their use of identifiers to differentiate among biological products.

Many active pharmacovigilance systems, have limited ability to track to its manufacturer a biological product that shares the same proper name with other biological products.

Other product identifiers, such as NDC numbers, are not routinely recorded in billing and patient records in many clinical settings in which biological products are dispensed and administered.

Nonproprietary names that include distinguishing suffixes can serve as a key element to identify specific products in billing and claims records used for active pharmacovigilance.

Robust Pharmacovigilance is essential to ensure patient safety. The FDA expects that biological products that include nonproprietary names with FDA-designated suffixes will assist in the timely and precise identification of the product associated with adverse events in all settings of care

Process for Suffix Review

Suffix evaluation by FDA occurs as part of the BLA review

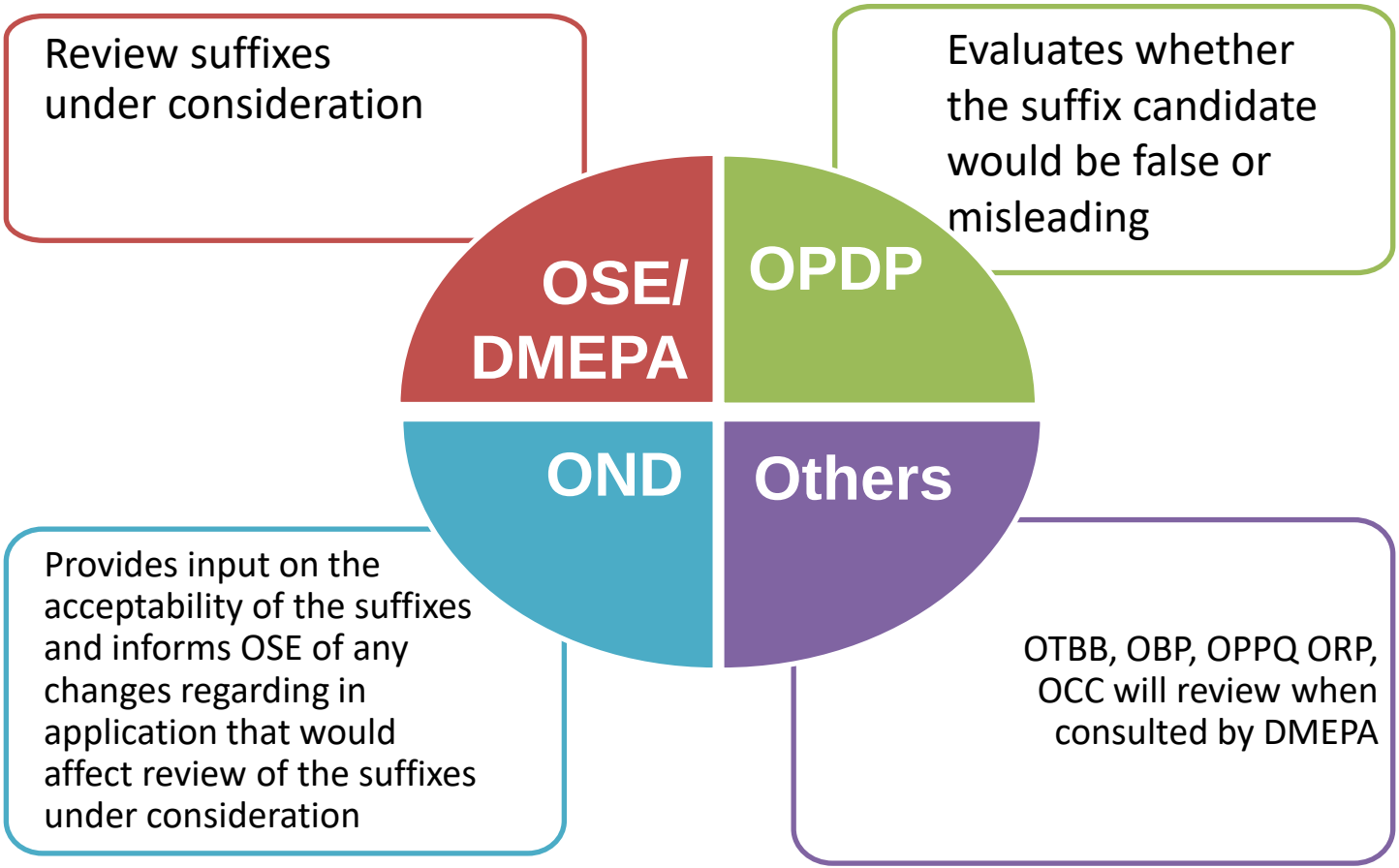
- In CDER, coordinated by Division of Medication Error Prevention and Analysis (DMEPA)
- In CBER, coordinated by the Advertising and Promotional Labeling Branch

FDA may generate a suffix for designation in the proper name, if an applicant

- Requests an FDA-generated suffix be assigned to their product
- Does not request FDA review of proposed suffix(es)
- Does not request review of a suffix FDA finds acceptable or within an appropriate time frame to allow FDA sufficient time to review

FDA encourages applicants requesting FDA review of suffixes to conduct due diligence on their proposed suffixes

Suffix Review: Roles



How FDA evaluates suffixes

FDA's review begins by assessing format looking to see whether the suffix is:

- Composed of four lower-case letters of which at least three are distinct
- Does not contain numerals and other symbols
- Devoid of meaning
- Unique to each product
- Nonproprietary
- Attached to the core name with a hyphen

How FDA evaluates suffixes

If the suffix format does not raise any concerns, FDA proceeds to review each suffix to determine that it will not:

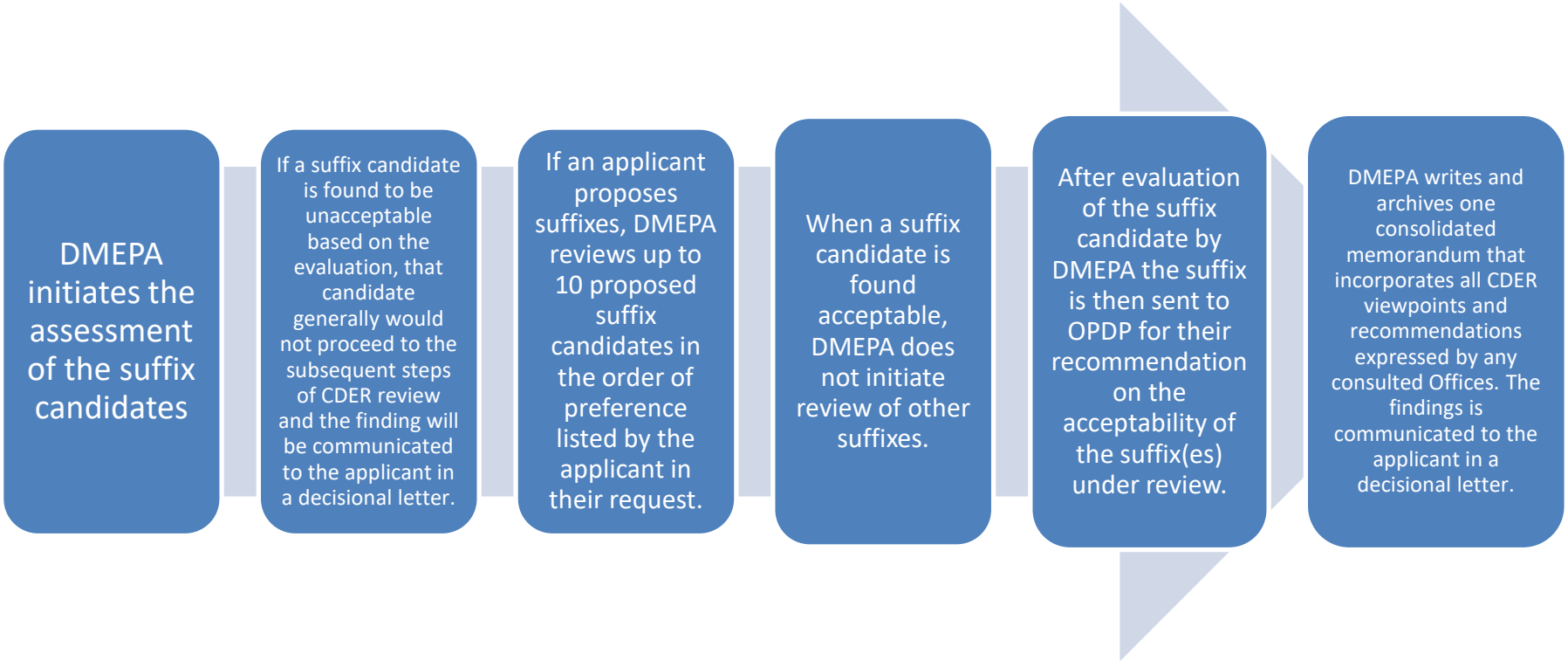
- Include abbreviations commonly used in clinical practice in a manner that may lead the suffix to be misinterpreted as another element on the prescription or order
- Contain or suggest any drug substance name or core name
- Look similar to or be capable of being mistaken for the name of a currently marketed product (e.g. should not increase the risk of confusion or medical errors with the product and/or other products in the clinical setting)
- Be too similar to any other FDA-designated nonproprietary name suffix
- Look similar to or otherwise connote the name of the license holder
- Be false or misleading, such as making representation with respect to safety or efficacy

How FDA identifies similar names and similar suffixes

To identify similar drug names	FDA uses the Phonetic and Orthographic Computerized Analysis (POCA) tool and sets the program to search those names listed on Drugs@FDA and pending proposed proprietary names.
To identify similar suffixes	FDA uses the POCA tool and sets the program to search for suffixes that are similar in spelling, writing or pronunciation to those suffixes that have been conditionally accepted or approved by FDA*

*FDA maintains two separate repositories of suffixes using the POCA tool: one will be publicly accessible and allow users to search their suffix candidate against only those suffixes that are associated with approved biological products, the other non-public repository will consist of those suffixes associated with INDs and pending BLAs and will only be accessible to FDA staff to use in their review of suffix candidates.

Process for Suffix Review



Question 1

FDA may object to a suffix if the suffix:

A. Includes abbreviations that can be misinterpreted as another element on the prescription or order

B. Is too similar to any other FDA-designated nonproprietary name suffix

C. Looks similar to or otherwise connotes the name of the license holder

D. All of the above

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A. Includes abbreviations that can be misinterpreted as another element on the prescription or order

B. Is too similar to any other FDA-designated nonproprietary name suffix

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D. All of the above

Question 2

The suffix should:

A. Be composed of four lower-case letters of which at least three are distinct

B. Should contain at least one numeral

C. Should not be attached to the core name with a hyphen

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Resources

- Guidance for Industry- Nonproprietary Naming of Biological Products
- Draft Guidance for Industry- Nonproprietary Naming of Biological Products: Update
- MAPP 6720.5 Procedures for Handling Requests for Nonproprietary Name Suffix Review for Biological Products Newly Licensed Under Section 351 of the PHS Act


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