Nonproprietary Naming of Biological Products

Guidance for Industry

DRAFT GUIDANCE

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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

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Contains Nonbinding Recommendations

Draft — Not for Implementation

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Nonproprietary Naming of Biological Products

Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

This guidance describes FDA's current thinking on the need for biological products licensed under the Public Health Service Act (PHS Act) to bear a nonproprietary name that includes an FDA-designated suffix. FDA's current thinking is that shared nonproprietary names are not appropriate for all biological products. There is a need to clearly identify biological products to improve pharmacovigilance and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable. Accordingly, for all biological products, FDA intends to designate a nonproprietary name that includes a suffix composed of four lowercase letters. Each suffix will be incorporated in the nonproprietary name of the product. This naming convention is applicable to biological products previously licensed and newly licensed under section 351(a) of the PHS Act or 351(k) of the PHS Act, as added by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The nonproprietary name designated for originator biological products, related biological products, and biosimilar products will include a unique suffix. However, as discussed in section IV.C of this guidance, FDA is seeking comment on whether the nonproprietary name for an interchangeable product should include a unique suffix, or should share the same suffix as its reference product.

By differentiating among biological products that have not been determined to be interchangeable, the goal of this naming convention is to help minimize inadvertent substitution. Inadvertent substitution may lead to unintended alternating or switching of biological products that have not been determined by FDA to be interchangeable. This naming convention may also facilitate pharmacovigilance for multiple biological products containing related drug substances when other means to track a specific dispensed product are not readily accessible, as described in section III.B.2 of this guidance. Application of the naming convention to all biological products is intended to (1) encourage routine use of designated suffixes in ordering, prescribing, dispensing, and recordkeeping practices and (2) avoid inaccurate perceptions of the safety and

[1] This guidance has been prepared by the Office of Medical Policy in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research at the Food and Drug Administration.

effectiveness of biological products based on their licensure pathway, as described in detail in this guidance.

This guidance provides information to industry, the health care community, other regulatory agencies, and the public on FDA's rationale for this naming convention. This guidance is also intended to assist applicants and application holders in proposing the suffix to be used as part of a biological product's nonproprietary name. The nonproprietary name designated by FDA in the license for a biological product licensed under the PHS Act is its *proper name*, and the term *proper name* will be used throughout this guidance.[2]

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. SCOPE

This guidance describes FDA's approach to designating the *proper name* for biological products licensed under section 351(a) of the PHS Act and for biosimilar products and interchangeable products licensed under section 351(k) of the PHS Act. These products are defined or described for the purposes of this guidance as follows:

> *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide) or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (see section 351(i)(1) of the PHS Act).
>
> *Related biological product* means a biological product submitted in a biologics license application (BLA) under section 351(a) of the PHS Act (i.e., a stand-alone BLA) for which there is a previously licensed biological product submitted in a different section 351(a) BLA that contains a drug substance for which certain nomenclature conventions (e.g., United States Adopted Names (USAN) Guiding Principles[3]) would be expected to provide for use of the same drug substance name.[4]

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[2] Section 351(a)(1)(B)(i) of the PHS Act (42 U.S.C. 262(a)(1)(B)(i) and § 600.3(k) (21 CFR 600.3(k)).

[3] The United States Pharmacopeial Convention, 2015, Guiding Principles for Coining United States Adopted Names for Drugs. In *2015 USP Dictionary of USAN and International Drug Names*. http://www.uspusan.com/usan/pub/index1.html.

[4] FDA's description of a biological product as a *related biological product* in this guidance is separate from any determination FDA may make about whether a related biological product is eligible for a period of exclusivity under section 351(k)(7) of the PHS Act.

77
78 *Originator biological product* means a biological product submitted in a BLA under
79 section 351(a) of the PHS Act (i.e., a stand-alone BLA) for which there is no previously
80 licensed biological product submitted under section 351(a) that is a related biological
81 product.
82
83 *Biosimilar product* means a biological product submitted in a 351(k) application that has
84 been shown to be highly similar to the reference product[5] notwithstanding minor
85 differences in clinically inactive components, and for which there are no clinically
86 meaningful differences between the biological product and the reference product in terms
87 of the safety, purity, and potency of the product (see section 351(i)(2) of the PHS Act).
88
89 *Interchangeable product* means a biological product that has been shown to meet the
90 standards described in section 351(k)(4) of the PHS Act and may be substituted for the
91 reference product without the intervention of the health care provider who prescribed the
92 reference product (see section 351(i)(3) of the PHS Act).
93
94 FDA intends to apply this naming convention to both newly licensed and previously licensed
95 biological products. As discussed further in section III.B of this guidance, in the case of
96 biological products previously licensed under the PHS Act, the revised *proper name* generally
97 would be the product's original *proper name* plus the designated suffix attached with a hyphen.[6]
98 As described in section IV.A.2 of this guidance, FDA is continuing to consider the most effective
99 regulatory approach to implement this naming convention for previously licensed products but,
100 in the near term, intends to assign distinguishing suffixes to a limited group of these products.
101
102 This guidance does not apply to biological products for which a proper name is provided in the
103 regulations (e.g., 21 CFR part 640) or to certain categories of biological products for which there
104 are well-established, robust identification and tracking systems to ensure safe dispensing
105 practices and optimal pharmacovigilance (ISBT 128 for cord blood products).
106
107 FDA is continuing to consider the transition provisions of section 7002(e)(2) through (e)(4) of
108 the BPCI Act that apply to biological products submitted or approved under the Federal Food,
109 Drug, and Cosmetic Act (FD&C Act), including how those provisions may impact
110 nonproprietary naming of products to which those provisions apply.
111

[5] *Reference product* means the single biological product licensed under section 351(a) of the PHS Act against which a biological product is evaluated in a 351(k) application (section 351(i)(4) of the PHS Act).

[6] The revised proper name *generally* would be the product's original proper name plus the designated suffix, but there would be limited exceptions. For example, for tbo-filgrastim, FDA is proposing to change the proper name by attaching a distinguishing suffix to the *core name* of "filgrastim," rather than attaching a distinguishing suffix to the original proper name of "tbo-filgrastim." Please see section IV for a discussion of how FDA determines a biological product's *core name.*

III. BACKGROUND

A. The Biologics Price Competition and Innovation Act of 2009

With the passage of the BPCI Act,[7] which established an abbreviated licensure pathway for products demonstrated to be biosimilar to or interchangeable with an FDA-licensed reference product, a growing number of biological products will be entering the marketplace.

Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. Section 351(i) defines *biosimilarity* to mean "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "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). To meet the additional standard of *interchangeability*, an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act). Interchangeable products may be substituted for the reference product by a pharmacist without the intervention of the prescribing health care provider (see section 351(i)(3) of the PHS Act).

B. Evaluation of the Appropriate Naming Convention

The *proper name* of a biological product reflects certain scientific characteristics of the product, such as chemical structure and pharmacological properties. This name is different from a *proprietary* name, which generally is trademarked and registered for private use. For biological products licensed under the PHS Act, FDA designates the *proper name* in the license for use upon each package of the biological product (see section 351(a)(1)(B)(i) of the PHS Act and § 600.3(k)). Among other things, the *proper name* of a biological product helps health care providers identify the product's drug substance and distinguish biological products from one another.

As part of FDA's implementation of the BPCI Act, the Agency requested public comment on its development of a framework for safe use and optimal pharmacovigilance for biosimilar products and interchangeable products that is informed by current experience and industry best practices, including the role of a product's *proper name*.

FDA has evaluated comments received on the approaches to naming biosimilar products and interchangeable products.[8] In light of the issues considered for biosimilar products and

[7] Sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Public Law 111-148).

interchangeable products, FDA also evaluated its approach to designating *proper names* for biological products licensed under section 351(a) of the PHS Act.

In implementing the BPCI Act, FDA has carefully considered the appropriate naming convention to maximize the success of biosimilar products and interchangeable products and to help ensure the safety of patients receiving biological products licensed under the PHS Act.

1. Ensuring Safe Use for Biological Products

FDA considers the safety of patients who are taking any medical product to be of the utmost importance. Biological products generally consist of large, complex molecules and raise unique safety concerns related to immunogenicity. FDA believes the nonproprietary naming convention for biological products should help prevent inadvertent substitution. Inadvertent substitution may lead to unintended alternating or switching of biological products that are not determined by FDA to be interchangeable with each other. This naming convention should facilitate safe use and protect the safety of patients.

Related biological products may be licensed for different indications. Biosimilar products may be licensed for fewer than all indications for which the reference product is licensed. Likewise, related biological products and biosimilar products may be licensed for fewer than all routes of administration and may be packaged in different delivery systems (e.g., pre-filled syringe instead of a vial) than approved for the originator biological product. If originator, related, and biosimilar biological products all share the same *proper name*, inadvertent substitution may lead to medication errors. For example, a patient could inadvertently receive a product with a different delivery system or route of administration than was prescribed, which may lead to confusion and dosing errors.

Confusion may also arise among health care providers who, based on their experience with small-molecule drugs and generic versions of those drugs, may incorrectly assume that FDA has determined biological products with the same *proper name* to be interchangeable. Information on alternating or switching between a proposed product and its reference product is required to support a demonstration of interchangeability, but is not required to support a demonstration of biosimilarity (see section 351(k)(4) of the PHS Act). Furthermore, applications for related biological products are not required to include any comparative data to any other biological product in support of licensure (see section 351(a) of the PHS Act). Although many biological products may have proprietary names, many health care systems mainly use *proper names* instead of proprietary names for ordering, prescribing, and dispensing products.

FDA believes that designation of a *proper name* that includes a distinguishing suffix for biological products that have not been determined to be interchangeable is the best mechanism to facilitate their safe use.

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[8] See, e.g., notices that published in the *Federal Register*, "Approval Pathway for Biosimilar and Interchangeable Biological Products; Public Hearing; Request for Comments" (75 FR 61497, October 5, 2010) and "Draft Guidances Relating to the Development of Biosimilar Products; Public Hearing; Request for Comments" (77 FR 12853, March 2, 2012) and other public dockets established by FDA.

2. Enhancing Biological Product Pharmacovigilance

The Agency considers appropriate pharmacovigilance fundamentally important for all biological products. Although safety of biological products is rigorously assessed before approval, safety issues that are specific to a manufacturer may arise after approval with any marketed product. Therefore, a robust pharmacovigilance program is essential to help ensure patient safety. To ensure continued safety of a biological product, appropriate pharmacovigilance necessitates that FDA have the ability to track adverse events to a specific manufacturer (and as appropriate, site or lot for a particular biological product) and that surveillance systems be able to detect safety signals throughout the lifecycle of a product so that the Agency and the manufacturer can act swiftly and in a targeted manner to identify and address a problem. If the Agency cannot identify a biological product's manufacturer, remedial action (including recall) may need to include a broader set of products, which may restrict patient access to safe and effective products for which no such problem exists.

Pharmacovigilance systems, both active and passive, vary in their use of identifiers to differentiate among biological products; and these identifiers may include the proprietary name, *proper name*, manufacturer, national drug code (NDC) number, lot number, and billing codes. However, many active pharmacovigilance systems, which generally identify adverse events by querying privately held electronic health care data such as administrative and billing data, have limited ability to track to its manufacturer a biological product that shares the same *proper name* with other biological products. For example, NDC numbers are not routinely recorded in billing and patient records in many clinical settings in which biological products are dispensed and administered. Similarly, in many passive pharmacovigilance systems, proprietary names and NDC numbers are often not included in adverse event reports. As a result, the use of distinct proprietary names or NDC numbers is insufficient to address concerns regarding pharmacovigilance. The Agency's approach to naming biological products will provide another critical tool for accurately identifying and facilitating pharmacovigilance for these products.

3. Advancing Appropriate Practices and Perceptions Regarding Biological Products

With the introduction of more biological products, FDA believes it is important to encourage routine use of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices for biological products irrespective of their licensure pathway and their date of licensure. The designated suffix will provide a consistent, readily available and recognizable mechanism for patients and health care professionals, including providers and pharmacists, to correctly identify these products.

This naming convention would have the added benefit of avoiding inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway. The safety and effectiveness of biological products is rigorously assessed before approval. A number of comments have expressed concern that requiring distinguishable *proper names* only for products licensed under section 351(k) of the PHS Act – but not for the reference product licensed under 351(a) of the PHS Act – will adversely affect use of these new products by health care providers and patients. Specifically, the comments expressed concern that such an approach will be

misinterpreted as indicating that biosimilar products and interchangeable products differ from their reference products in a clinically meaningful way or are inferior to their reference products for their approved conditions of use. FDA shares the concern that such an approach could lead to inaccurate and scientifically unfounded assertions of inferiority or clinically meaningful difference of an approved biosimilar product for its approved indications. FDA anticipates that use of *proper names* with designated suffixes for biological products, irrespective of licensure pathway and date of licensure, will avoid any inaccurate perceptions of their safety and effectiveness.

Through FDA's implementation of the BPCI Act's standards for biosimilarity and interchangeability, FDA can ensure that products it determines to be biosimilar to or interchangeable with a reference product can be relied upon by providers and patients to be safe and effective for the approved conditions of use.

4. Prospective and Retrospective Application of Naming Convention

FDA's current thinking is that a *proper name* that includes a designated suffix is warranted for biological products newly licensed and products previously licensed. As with prospective application of the naming convention, retrospective application of the convention will help to (1) prevent a patient from receiving a product different from what was intended to be prescribed; (2) facilitate manufacturer-specific pharmacovigilance by providing a means of determining which biological product is dispensed to patients; (3) encourage routine use of designated suffixes in ordering, prescribing, dispensing, and recordkeeping practices for these products; and (4) advance accurate perceptions of biological products.

IV. FRAMEWORK FOR DESIGNATING THE PROPER NAME OF A BIOLOGICAL PRODUCT

FDA's naming convention for licensed biological products described in this guidance will be a *proper name* for all biological products within the scope of this guidance that will include a *core name*[9] and a designated suffix. For interchangeable products, FDA is considering whether the designated suffix should be unique or should be the same as its reference product.

For originator biological products, FDA intends to use a *core name* that is the name adopted by the USAN Council[10] for the drug substance when available. If the biological product is a related, biosimilar, or interchangeable product, the *core name* will be the name of the drug substance

[9] The *core name* is the component shared among all related biological products as part of the *proper name*. Two examples of a *core name* are filgrastim and epoetin alfa. The *proper name* for all biological products will include a designated suffix composed of four lowercase letters attached to the *core name* with a hyphen.

[10] For more information on the USAN Council and its nomenclature activities, including information on biological classes for which USAN nomenclature exists, please see the USAN Council's Web page (available at http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council.page).

contained in the relevant previously licensed product.[11] A designated suffix composed of four lowercase letters will be added to the *core name* of each product and will be attached with a hyphen.[12] Importantly, use of a shared *core name* will indicate a relationship among products. The placement of the identifier as a suffix, rather than a prefix, should result in the biological products with the same core name being grouped together in electronic databases to help health care providers identify these products.

For example, for products sharing the *core name* replicamab, those *proper names* may be displayed as follows:

replicamab-cznm
replicamab-hixf

And, for products sharing the *core name* putonastim alfa, those *proper names* may be displayed as follows:

putonastim alfa-jnzt
putonastim alfa-kngx

In designating *proper names* for related biological products, the Agency, to date, has in some instances designated a *proper name* that includes an identifier attached as a prefix to distinguish the products from previously licensed biological products; for example, ado-trastuzumab emtansine. In this case, designation of a *proper name* that includes a unique prefix was necessary to minimize certain medication errors and to facilitate pharmacovigilance. FDA determined that a unique *proper name* was necessary for ado-trastuzumab emtansine to distinguish the product from trastuzumab, a previously licensed biological product submitted in a different BLA.[13] FDA may continue such practices on a limited basis, where appropriate, to ensure patient safety when the Agency determines that a suffix as contemplated by this guidance is insufficient alone.

[11] FDA will work with stakeholders that play a role in national drug naming and listing to help ensure that the suffixes added to the *core name* of biological products are recorded appropriately in drug listing systems.

[12] FDA determined that a hyphen should separate the shared *core name* from the suffix. A hyphen is a common punctuation mark used in writing and electronic systems; it is a readily recognized mark. Another punctuation mark, such as an underscore, may not be normally used in handwriting and may not be readily seen in handwriting, electronic systems, or both.

[13] As described in the BLA submission for ado-trastuzumab emtansine, medication errors involving administration of the wrong drug (trastuzumab emtansine versus trastuzumab) during clinical trials resulted in serious adverse events.

A. Biological Products Submitted Under Section 351(a) of the PHS Act

1. Prospective Naming of Biological Products

An applicant for a biological product submitted under section 351(a) of the PHS Act should propose a suffix composed of four lowercase letters for use as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure (see section V of this guidance).

2. Retrospective Naming of Biological Products

As discussed in sections II and III of this guidance, FDA intends to apply the naming convention described in this guidance to biological products previously licensed under section 351 of the PHS Act. FDA is considering the most effective regulatory approach to implement this naming convention for previously licensed products, including rulemaking, and will provide additional information. In the near term, however, FDA intends to assign distinguishing suffixes to a limited group of (1) biological products that are referenced by approved or publicly announced pending biosimilar applications and (2) any related products to those reference products through rulemaking.

B. Biosimilar Products Submitted Under Section 351(k) of the PHS Act

An applicant for a proposed biosimilar product submitted under section 351(k) of the PHS Act should propose a suffix composed of four lowercase letters for use as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure (see section V of this guidance).

C. Interchangeable Products Submitted Under Section 351(k) of the PHS Act

FDA intends to apply the naming convention described in this guidance to interchangeable products licensed under section 351(k) of the PHS Act in an original application or a supplement and is considering two alternative approaches:

1. *Distinct from the reference product:* An applicant for a proposed interchangeable product submitted in an original application under section 351(k) of the PHS Act would propose a unique suffix composed of four lowercase letters for use as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure (see section V of this guidance). An applicant seeking a determination of interchangeability in a supplement to its 351(k) application would keep the existing suffix.

2. *Shared with the reference product:* An applicant for a proposed interchangeable product submitted in an original application or a supplement under 351(k) of the PHS Act would be assigned the same proper name and suffix as its reference product.

FDA seeks comment on these alternative approaches to the naming convention for interchangeable products.

V. PROCESS FOR PROPOSING A SUFFIX FOR THE PROPER NAME OF A BIOLOGICAL PRODUCT

The proposed suffix ***should***:

- Be four lowercase letters
- Be unique
- Be devoid of meaning

The proposed suffix ***should not:***

- Be promotional, such as by making misrepresentations with respect to safety or efficacy
- 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* designated by the USAN Council
- Look similar to or be 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 product's suffix designation

FDA encourages applicants to conduct due diligence on their proposed suffixes to ensure that no other restrictions apply to the proposed suffix's use in this context.

FDA expects that a proposed suffix will be appended to the core name of each biological product.

FDA encourages applicants to request FDA review of a proposed suffix for their products. If the naming convention is first applied to a new product, the request for FDA's review of the preferred suffix should occur during the investigational new drug application (IND) phase or at the time of BLA submission. For BLA holders seeking to propose a distinguishing suffix after approval, FDA recommends that a prior-approval labeling supplement be submitted. An applicant should submit no more than three proposed suffixes, as described in this section, in the order of the applicant's preference. We recommend including any supporting analyses of the proposed suffixes for FDA's consideration based on the factors described in this section.

VI. FDA'S APPROACH TO THE EVALUATION OF A PROPOSED SUFFIX FOR THE PROPER NAME OF BIOLOGICAL PRODUCTS

FDA will evaluate proposed suffixes against the factors described in section V of this guidance. FDA intends to use a combination of tools and methods to evaluate the proposed suffixes as appropriate. This evaluation will generally occur during the IND phase and will also be incorporated into the review of the marketing application. FDA will notify applicants of the suitability of the proposed suffix upon completion of the Agency's evaluation.

VII. PUBLICATION OF THE PURPLE BOOK: LISTS OF LICENSED BIOLOGICAL PRODUCTS WITH REFERENCE PRODUCT EXCLUSIVITY AND BIOSIMILARITY OR INTERCHANGEABILITY EVALUATIONS

FDA published the *Purple Book: Lists of Licensed Biological Products With Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* in September 2014, which is publicly available.[14] The Purple Book lists biological products, including any biosimilar products and interchangeable products, licensed by FDA under the PHS Act. The lists include the date on which a biological product was licensed under section 351(a) of the PHS Act and whether FDA evaluated the biological product for reference product exclusivity under section 351(k)(7) of the PHS Act.

The Purple Book also enables a user to readily see whether a biological product licensed under section 351(k) of the PHS Act has been determined by FDA to be biosimilar to or interchangeable with a reference product (a previously licensed biological product). The naming convention (proper names including a designated suffix) discussed in this guidance will facilitate use of the Purple Book. Biosimilar products and interchangeable products licensed under section 351(k) of the PHS Act will be listed under the reference product to which biosimilarity or interchangeability was demonstrated.

The Purple Book is composed of separate lists for those biological products regulated by CDER and CBER and will be updated online periodically.

[14] See http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm.