
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DRAFT GUIDANCE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)**

**August 2015
Labeling**

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Nonproprietary Naming of Biological Products

Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

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

43
44 This guidance provides information to industry, the health care community, other regulatory
45 agencies, and the public on FDA's rationale for this naming convention. This guidance is also
46 intended to assist applicants and application holders in proposing the suffix to be used as part of
47 a biological product's nonproprietary name. The nonproprietary name designated by FDA in the
48 license for a biological product licensed under the PHS Act is its *proper name*, and the term
49 *proper name* will be used throughout this guidance.²

50
51 In general, FDA's guidance documents do not establish legally enforceable responsibilities.
52 Instead, guidances describe the Agency's current thinking on a topic and should be viewed only
53 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
54 the word *should* in Agency guidances means that something is suggested or recommended, but
55 not required.

56 57 **II. SCOPE**

58
59 This guidance describes FDA's approach to designating the *proper name* for biological products
60 licensed under section 351(a) of the PHS Act and for biosimilar products and interchangeable
61 products licensed under section 351(k) of the PHS Act. These products are defined or described
62 for the purposes of this guidance as follows:

63
64 *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood,
65 blood component or derivative, allergenic product, protein (except any chemically
66 synthesized polypeptide) or analogous product, or arsphenamine or derivative of
67 arsphenamine (or any other trivalent organic arsenic compound), applicable to the
68 prevention, treatment, or cure of a disease or condition of human beings (see section
69 351(i)(1) of the PHS Act).

70
71 *Related biological product* means a biological product submitted in a biologics license
72 application (BLA) under section 351(a) of the PHS Act (i.e., a stand-alone BLA) for
73 which there is a previously licensed biological product submitted in a different section
74 351(a) BLA that contains a drug substance for which certain nomenclature conventions
75 (e.g., United States Adopted Names (USAN) Guiding Principles³) would be expected to
76 provide for use of the same drug substance name.⁴

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.

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Originator biological product means a biological product submitted in a BLA under section 351(a) of the PHS Act (i.e., a stand-alone BLA) for which there is no previously licensed biological product submitted under section 351(a) that is a related biological product.

Biosimilar product means a biological product submitted in a 351(k) application that has been shown to be highly similar to the reference product⁵ 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).

Interchangeable product means a biological product that has been shown to meet the standards described in section 351(k)(4) of the PHS Act and may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product (see section 351(i)(3) of the PHS Act).

FDA intends to apply this naming convention to both newly licensed and previously licensed biological products. As discussed further in section III.B of this guidance, in the case of biological products previously licensed under the PHS Act, the revised *proper name* generally would be the product's original *proper name* plus the designated suffix attached with a hyphen.⁶ As described in section IV.A.2 of this guidance, FDA is continuing to consider the most effective regulatory approach to implement this naming convention for previously licensed products but, in the near term, intends to assign distinguishing suffixes to a limited group of these products.

This guidance does not apply to biological products for which a proper name is provided in the regulations (e.g., 21 CFR part 640) or to certain categories of biological products for which there are well-established, robust identification and tracking systems to ensure safe dispensing practices and optimal pharmacovigilance (ISBT 128 for cord blood products).

FDA is continuing to consider the transition provisions of section 7002(e)(2) through (e)(4) of the BPCI Act that apply to biological products submitted or approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act), including how those provisions may impact nonproprietary naming of products to which those provisions apply.

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*.

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112 **III. BACKGROUND**

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114 **A. The Biologics Price Competition and Innovation Act of 2009**

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

119

120 Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the
121 requirements for an application for a proposed biosimilar product and an application or a
122 supplement for a proposed interchangeable product. Section 351(i) defines *biosimilarity* to mean
123 “that the biological product is highly similar to the reference product notwithstanding minor
124 differences in clinically inactive components” and that “there are no clinically meaningful
125 differences between the biological product and the reference product in terms of the safety,
126 purity, and potency of the product” (see section 351(i)(2) of the PHS Act). To meet the
127 additional standard of *interchangeability*, an applicant must provide sufficient information to
128 demonstrate biosimilarity and also to demonstrate that the biological product can be expected to
129 produce the same clinical result as the reference product in any given patient and, if the
130 biological product is administered more than once to an individual, the risk in terms of safety or
131 diminished efficacy of alternating or switching between the use of the biological product and the
132 reference product is not greater than the risk of using the reference product without such
133 alternation or switch (see section 351(k)(4) of the PHS Act). Interchangeable products may be
134 substituted for the reference product by a pharmacist without the intervention of the prescribing
135 health care provider (see section 351(i)(3) of the PHS Act).

136

137 **B. Evaluation of the Appropriate Naming Convention**

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139 The *proper name* of a biological product reflects certain scientific characteristics of the product,
140 such as chemical structure and pharmacological properties. This name is different from a
141 *proprietary* name, which generally is trademarked and registered for private use. For biological
142 products licensed under the PHS Act, FDA designates the *proper name* in the license for use
143 upon each package of the biological product (see section 351(a)(1)(B)(i) of the PHS Act and
144 § 600.3(k)). Among other things, the *proper name* of a biological product helps health care
145 providers identify the product’s drug substance and distinguish biological products from one
146 another.

147

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

152

153 FDA has evaluated comments received on the approaches to naming biosimilar products and
154 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).

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

157
158 In implementing the BPCI Act, FDA has carefully considered the appropriate naming convention
159 to maximize the success of biosimilar products and interchangeable products and to help ensure
160 the safety of patients receiving biological products licensed under the PHS Act.

161
162 *1. Ensuring Safe Use for Biological Products*

163
164 FDA considers the safety of patients who are taking any medical product to be of the utmost
165 importance. Biological products generally consist of large, complex molecules and raise unique
166 safety concerns related to immunogenicity. FDA believes the nonproprietary naming convention
167 for biological products should help prevent inadvertent substitution. Inadvertent substitution
168 may lead to unintended alternating or switching of biological products that are not determined by
169 FDA to be interchangeable with each other. This naming convention should facilitate safe use
170 and protect the safety of patients.

171
172 Related biological products may be licensed for different indications. Biosimilar products may
173 be licensed for fewer than all indications for which the reference product is licensed. Likewise,
174 related biological products and biosimilar products may be licensed for fewer than all routes of
175 administration and may be packaged in different delivery systems (e.g., pre-filled syringe instead
176 of a vial) than approved for the originator biological product. If originator, related, and
177 biosimilar biological products all share the same *proper name*, inadvertent substitution may lead
178 to medication errors. For example, a patient could inadvertently receive a product with a
179 different delivery system or route of administration than was prescribed, which may lead to
180 confusion and dosing errors.

181
182 Confusion may also arise among health care providers who, based on their experience with
183 small-molecule drugs and generic versions of those drugs, may incorrectly assume that FDA has
184 determined biological products with the same *proper name* to be interchangeable. Information
185 on alternating or switching between a proposed product and its reference product is required to
186 support a demonstration of interchangeability, but is not required to support a demonstration of
187 biosimilarity (see section 351(k)(4) of the PHS Act). Furthermore, applications for related
188 biological products are not required to include any comparative data to any other biological
189 product in support of licensure (see section 351(a) of the PHS Act). Although many biological
190 products may have proprietary names, many health care systems mainly use *proper names*
191 instead of proprietary names for ordering, prescribing, and dispensing products.

192
193 FDA believes that designation of a *proper name* that includes a distinguishing suffix for
194 biological products that have not been determined to be interchangeable is the best mechanism to
195 facilitate their safe use.

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.

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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

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

250
251 Through FDA's implementation of the BPCI Act's standards for biosimilarity and
252 interchangeability, FDA can ensure that products it determines to be biosimilar to or
253 interchangeable with a reference product can be relied upon by providers and patients to be safe
254 and effective for the approved conditions of use.

255 256 4. *Prospective and Retrospective Application of Naming Convention*

257
258 FDA's current thinking is that a *proper name* that includes a designated suffix is warranted for
259 biological products newly licensed and products previously licensed. As with prospective
260 application of the naming convention, retrospective application of the convention will help to
261 (1) prevent a patient from receiving a product different from what was intended to be prescribed;
262 (2) facilitate manufacturer-specific pharmacovigilance by providing a means of determining
263 which biological product is dispensed to patients; (3) encourage routine use of designated
264 suffixes in ordering, prescribing, dispensing, and recordkeeping practices for these products; and
265 (4) advance accurate perceptions of biological products.

266 267 **IV. FRAMEWORK FOR DESIGNATING THE PROPER NAME OF A** 268 **BIOLOGICAL PRODUCT**

269
270 FDA's naming convention for licensed biological products described in this guidance will be a
271 *proper name* for all biological products within the scope of this guidance that will include a *core*
272 *name*⁹ and a designated suffix. For interchangeable products, FDA is considering whether the
273 designated suffix should be unique or should be the same as its reference product.

274
275 For originator biological products, FDA intends to use a *core name* that is the name adopted by
276 the USAN Council¹⁰ for the drug substance when available. If the biological product is a related,
277 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>).

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

284

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

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288 replicamab-cznm

289 replicamab-hixf

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

293

294 putonastim alfa-jnzt

295 putonastim alfa-kngx

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

307

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.

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

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1. Prospective Naming of Biological Products

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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).

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2. Retrospective Naming of Biological Products

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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.

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

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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).

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

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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:

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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.

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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.

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

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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.

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Draft — Not for Implementation

397 **VI. FDA’S APPROACH TO THE EVALUATION OF A PROPOSED SUFFIX FOR** 398 **THE PROPER NAME OF BIOLOGICAL PRODUCTS**

399
400 FDA will evaluate proposed suffixes against the factors described in section V of this guidance.
401 FDA intends to use a combination of tools and methods to evaluate the proposed suffixes as
402 appropriate. This evaluation will generally occur during the IND phase and will also be
403 incorporated into the review of the marketing application. FDA will notify applicants of the
404 suitability of the proposed suffix upon completion of the Agency’s evaluation.

405 406 **VII. PUBLICATION OF THE PURPLE BOOK: LISTS OF LICENSED BIOLOGICAL** 407 **PRODUCTS WITH REFERENCE PRODUCT EXCLUSIVITY AND BIOSIMILARITY** 408 **OR INTERCHANGEABILITY EVALUATIONS**

409
410 FDA published the *Purple Book: Lists of Licensed Biological Products With Reference Product*
411 *Exclusivity and Biosimilarity or Interchangeability Evaluations* in September 2014, which is
412 publicly available.¹⁴ The Purple Book lists biological products, including any biosimilar
413 products and interchangeable products, licensed by FDA under the PHS Act. The lists include
414 the date on which a biological product was licensed under section 351(a) of the PHS Act and
415 whether FDA evaluated the biological product for reference product exclusivity under section
416 351(k)(7) of the PHS Act.

417
418 The Purple Book also enables a user to readily see whether a biological product licensed under
419 section 351(k) of the PHS Act has been determined by FDA to be biosimilar to or
420 interchangeable with a reference product (a previously licensed biological product). The naming
421 convention (proper names including a designated suffix) discussed in this guidance will facilitate
422 use of the Purple Book. Biosimilar products and interchangeable products licensed under section
423 351(k) of the PHS Act will be listed under the reference product to which biosimilarity or
424 interchangeability was demonstrated.

425
426 The Purple Book is composed of separate lists for those biological products regulated by CDER
427 and CBER and will be updated online periodically.

428
429

¹⁴ See

<http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm>.