
Nonproprietary Naming of Biological Products

Guidance for Industry

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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The information collection provisions in this guidance regarding submission of proposed suffixes are under OMB review and are not for current implementation.
See additional PRA statement in section VII of this guidance.

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This guidance represents 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 office 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*² that includes an FDA-designated suffix. Under this naming convention, the nonproprietary name designated for each *originator biological product*, *related biological product*, and *biosimilar product* will be a proper name that is a combination of the *core name* and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters.³ The suffix format described in this guidance is applicable to 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. FDA is continuing to consider the appropriate suffix format for *interchangeable products*.

This naming convention will facilitate pharmacovigilance for originator biological products, related biological products, and biosimilar products containing related drug substances when other means to track a specific dispensed product are not readily accessible or available, as described in section IV.A of this guidance. Distinguishable nonproprietary names will also facilitate accurate identification of these biological products by health care practitioners and patients. Further, distinguishing suffixes should help minimize inadvertent substitution of any such products that have not been determined to be interchangeable. Application of the naming convention to biological products licensed under the PHS Act should (1) encourage routine use of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices and (2) avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway, as described in detail in this guidance.

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.

² See the Glossary for definitions and usage of specific terms used throughout this guidance.

³ The nonproprietary name designated by FDA in the license for a biological product licensed under the PHS Act is its proper name (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)).

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This guidance provides information to industry, the health care community, other regulatory agencies, and the public on FDA's rationale for this naming convention. It is also intended to assist applicants and license holders in proposing the suffix to be incorporated in the nonproprietary name (referred to throughout this guidance as the *proper name*) for an originator biological product, a related biological product, or a biosimilar product.

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 originator and related biological products licensed under section 351(a) of the PHS Act and for biosimilar products licensed under section 351(k) of the PHS Act. FDA intends to apply a naming convention to interchangeable products that will feature a core name and a suffix included in the proper name; however, FDA is continuing to consider the appropriate format of the suffix for these products. FDA intends to apply the naming convention discussed in this guidance to both newly licensed and previously licensed biological products. As discussed further in section V of this guidance, the revised proper name of biological products previously licensed under the PHS Act generally would include the product's original proper name serving as the core name plus the distinguishing suffix attached with a hyphen. FDA is continuing to consider the process for implementation of this naming convention for previously licensed products but, in the near term, intends to assign distinguishing suffixes to a limited group of these products⁴ and also will accept submissions of prior approval labeling supplements that include proposed suffixes.

This guidance also will apply to those biological products that are approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) on or before March 23, 2020, when such products are deemed to be licensed under section 351 of the PHS Act on March 23, 2020 (section 7002(e)(2) through (e)(4) of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act)).⁵ FDA intends to provide additional guidance regarding administrative issues associated with the transition (including the process for implementing the naming convention described in this guidance).

⁴ The Agency published a proposed rule in the *Federal Register* of August 28, 2015 (80 FR 52224) ("Designation of Official Names and Proper Names for Certain Biological Products").

⁵ See the draft guidance for industry *Implementation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009*. When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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For the purposes of this document, unless otherwise specified, references to biological products include biological products licensed under the PHS Act, such as therapeutic protein products, vaccines, allergenic products, and blood derivatives, and do not include certain biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)), such as in vitro reagents (e.g., antibody to hepatitis B surface antigen, blood grouping reagents, hepatitis C virus encoded antigen) and blood donor screening tests (e.g., HIV and hepatitis C). Also, for the purposes of this document, unless otherwise specified, references to biological products do not include 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 (e.g., ISBT 128 for cord blood products and blood components).

III. BACKGROUND

A. The Biologics Price Competition and Innovation Act of 2009

With the passage of the BPCI Act,⁶ 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 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

⁶ Sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Public Law 111-148).

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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 21 CFR 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.⁷ In light of the issues considered for biosimilar products and 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.

IV. CONSIDERATIONS FOR NONPROPRIETARY NAMING OF ORIGINATOR BIOLOGICAL PRODUCTS, RELATED BIOLOGICAL PRODUCTS, AND BIOSIMILAR PRODUCTS

This section discusses the main considerations that led FDA to adopt the naming convention described in section V of this guidance.

A. Enhancing Biological Product Pharmacovigilance

The Agency considers appropriate pharmacovigilance fundamentally important for 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. To help ensure patient safety and allow the Agency and the manufacturer to swiftly identify and address a problem, FDA aims to track adverse events to a specific manufacturer (and as appropriate, to a lot or manufacturing site for a particular biological product) and allow surveillance systems to detect safety signals throughout the life cycle of a product. Identifying a biological product's manufacturer can help target remedial action (including recall) to avoid implicating a broader set of products for which no such problem exists.

⁷ See, for example, 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); "Draft Guidances Relating to the Development of Biosimilar Products; Public Hearing; Request for Comments" (77 FR 12853, March 2, 2012); "Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability" (80 FR 52296, August 28, 2015); and other public dockets established by FDA.

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Pharmacovigilance systems, both active and passive, vary in their use of identifiers to differentiate among biological products. 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. 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, and therefore the utility of these alternative identifiers in active pharmacovigilance is limited. Similarly, proprietary names and NDC numbers are often not included in adverse event reports. As a result, the use of alternative identifiers, including distinct proprietary names or NDC numbers, is insufficient to address concerns regarding pharmacovigilance.

Nonproprietary names that include distinguishing suffixes can serve as a key element to identify specific products in spontaneous adverse event reporting and to reinforce accurate product identification in billing and claims records used for active pharmacovigilance. Other product-specific identifiers, such as proprietary names or NDCs, may not be available or could change over time. A distinguishing suffix will also support the tracking of product-specific events over time, thereby enhancing the accurate attribution of product-specific adverse event reports.⁸

The Agency's approach to nonproprietary naming of biological products will provide another critical tool for accurately identifying and facilitating pharmacovigilance for originator biological products, related biological products, and biosimilar products.

B. Ensuring Safe Use for Biological Products

Biological products generally consist of large, complex molecules and raise unique safety concerns related to immunogenicity. FDA believes the nonproprietary naming convention for originator biological products, related biological products, or biosimilar 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 help to 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 than those approved for the

⁸See the draft guidance for industry *Postmarketing Safety Reporting for Human Drugs and Biological Products Including Vaccines*. When final, this guidance will represent FDA's current thinking on this topic.

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originator biological product. If originator biological products, related biological products, and biosimilar 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 among patients and result in 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). 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.

The naming convention discussed in this guidance will also facilitate use of the Purple Book⁹ for biological products. The Purple Book enables a user to readily see all licensed biological products and identify 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). 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.

C. 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 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. FDA believes it is likely that FDA-designated suffixes will be used routinely when identifying, describing, and recording use of biological products if such suffixes are present in the proper names of all biological products licensed under the PHS Act.

⁹ 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 at <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm>. The Purple Book is updated periodically to reflect FDA licensure of a biological product under section 351(a) or section 351(k) of the PHS Act and/or to reflect a determination regarding date of first licensure for a biological product licensed under section 351(a) of the PHS Act.

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The inclusion of an FDA-designated suffix in the nonproprietary name of biological products licensed under section 351(a) or 351(k) of the PHS Act should have the added benefit of helping to avoid 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. Through FDA's implementation of the BPCI Act's standards for biosimilarity and interchangeability, FDA can ensure that the 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. Applying this naming convention 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—could adversely affect health care provider and patient perceptions of these new products. Specifically, such an approach could be misinterpreted as indicating that biosimilar products differ from their reference products in a clinically meaningful way or are inferior to their reference products for their approved conditions of use.

D. Prospective and Retrospective Application of Naming Convention

FDA's current thinking is that a proper name that includes a distinguishing suffix is warranted for both newly licensed and previously licensed originator biological products, related biological products, and biosimilar products. As with prospective application of the naming convention, retrospective application will help (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 FDA-designated suffixes in ordering, prescribing, dispensing, and recordkeeping practices for these products; and (4) advance accurate perceptions of these biological products.

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

FDA's naming convention for biological products licensed under the PHS Act will be a proper name consisting of a core name¹⁰ and an FDA-designated suffix. Proper names designated by FDA for originator biological products, related biological products, and biosimilar products will include a combination of a core name and a distinguishing suffix.

For originator biological products, FDA intends to use a core name that is the adopted name designated by the USAN Council¹¹ for the relevant biological substance when available. If the biological product is a related biological product, a biosimilar product, or an interchangeable

¹⁰ Two examples of a *core name* are filgrastim and epoetin alfa. The *proper name* for all biological products will include a distinguishing suffix composed of four lowercase letters attached to the core name with a hyphen.

¹¹ The United States Pharmacopeial Convention, 2016, Guiding Principles for Coining United States Adopted Names for Drugs (2016 USP Dictionary of USAN and International Drug Names at <http://www.usp.usan.com/usan/pub/index1.html>).

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product, the core name will be the same as the core name identified in the proper name of the relevant previously licensed product.¹² A distinguishing suffix that is devoid of meaning and composed of four lowercase letters will be attached with a hyphen to the core name of each originator biological product, related biological product, or biosimilar product.¹³ 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 biological products with the same core name being grouped together in electronic databases to help health care providers locate and identify these products.¹⁴

To illustrate, the proper names for products sharing the core name replicamab may be displayed as follows:

replicamab-cznm
replicamab-hjxf

To illustrate, the proper names for products sharing the core name putonastim alfa may be displayed as follows:

putonastim alfa-jnzt
putonastim alfa-kngx

In designating proper names for related biological products, the Agency 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 including a prefix was necessary for ado-trastuzumab emtansine to distinguish the product from trastuzumab, a previously licensed biological product submitted in a different BLA.¹⁵ FDA may continue such practices on a limited basis, where appropriate, when the Agency determines that the designation of a prefix, in addition to a suffix as contemplated by this guidance, is necessary to ensure patient safety.

¹² 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.

¹³ 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.

¹⁴ The license holder and all distributors of a biological product should use the proper name designated by FDA in the license for that product.

¹⁵ 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. Prospective Naming of Biological Products Submitted Under Section 351(a) of the PHS Act

An applicant 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 VI of this guidance). Such submissions can be made during the investigational new drug application (IND) phase¹⁶ or at the time of BLA submission. An applicant should submit up to 10 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 guidance.

B. Retrospective Naming of Biological Products Licensed Under Section 351(a) of the PHS Act

A BLA holder may propose a suffix, as described in this guidance, for use in the proper name of currently licensed biological products held by the company by submitting a prior-approval labeling supplement to its BLA (see section VI of this guidance). As part of that labeling supplement, a BLA holder should submit up to 10 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 guidance.

C. Naming of 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 VI of this guidance). Such submissions can be made during the investigational new drug application (IND) phase¹⁷ or at the time of BLA submission. An applicant should submit up to 10 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 guidance.

¹⁶ A request for FDA review of a proposed suffix submitted during the investigational new drug application (IND) phase should be submitted no earlier than at the request for a pre-biologics license application (pre-BLA) meeting for biological products to be submitted under section 351(a) of the PHS Act.

¹⁷ A request for FDA review of a proposed suffix submitted during the investigational new drug application (IND) phase should be submitted no earlier than at the request for a biosimilar biological product development (BPD) type 4 meeting for biological products to be submitted under section 351(k) of the PHS Act.

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VI. PROPOSING A SUFFIX FOR THE PROPER NAME OF AN ORIGINATOR BIOLOGICAL PRODUCT, A RELATED BIOLOGICAL PRODUCT, OR A BIOSIMILAR PRODUCT

The proposed suffix *should*:

- Be unique
- Be devoid of meaning
- Be four lowercase letters of which at least three are distinct
- Be nonproprietary
- Be attached to the core name with a hyphen
- Be free of legal barriers that would restrict its usage

The proposed suffix *should not*:

- Be false or misleading, such as by making misrepresentations with respect to safety or efficacy
- Include numerals and other symbols aside from the hyphen attaching the suffix to the core name
- 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)
- Look similar to or otherwise connote the name of the license holder
- Be too similar to any other FDA-designated nonproprietary name suffix

FDA encourages applicants to conduct due diligence on their proposed suffixes to ensure that no other restrictions apply to use of the proposed suffix in this context. Any supporting information can be provided to FDA with the submission of the proposed suffix(es).

The final determination on the acceptability of a proposed suffix is based on FDA's review of all information and analyses described in this guidance, along with any information submitted by the sponsor.

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FDA will evaluate proposed suffixes against the factors described in this section and may consider other factors if they impact the utility of the suffix in meeting the goals of the naming convention articulated in this guidance. Upon completion of the Agency's evaluation, FDA will notify applicants if a proposed suffix is acceptable or if all of the proposed suffixes are determined to be unacceptable. If all of the proposed suffixes are determined to be unacceptable, applicants may submit additional proposed suffixes for FDA's consideration. If an applicant does not submit a suffix that FDA finds acceptable or does not propose suffix candidates within an appropriate time frame to allow sufficient time for FDA review, FDA may elect to assign a four-letter suffix for inclusion in the proper name designated in the license at the time FDA approves the application.

VII. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Specifically, the guidance recommends that applicants and application holders submit up to 10 proposed suffixes, in the order of the applicant's preference. FDA also recommends including any supporting analyses for FDA's consideration, demonstrating that the proposed suffixes meet the factors described in the final guidance.

FDA estimates that the time required to complete this information collection will average 420 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, rm. 6337, Silver Spring, MD 20993-0002

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information related to the submission of a BLA under section 351(k) of the PHS Act have been approved under OMB control number 0910-0719, and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The information collection provisions in this guidance, including resulting proposed modifications to the information collections approved under OMB control number 0910-0338, have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995 **and are not for current implementation**. Before implementing the information collection provisions contained in this guidance, we will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove those information collection provisions.

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GLOSSARY

Biosimilar Product means 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).

Core Name means the component shared among an originator biological product and any related biological product, biosimilar product, or interchangeable product as part of the proper names of those products. Two examples of a *core name* are filgrastim and epoetin alfa.

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).

Nonproprietary Name means a name unprotected by trademark rights that is in the public domain. It may be used by the public at large, both lay and professional.

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) that is not a related biological product.

Proper Name means the nonproprietary name designated by FDA in the license for a biological product licensed under the PHS Act.¹⁸

Proprietary Name means the trademark or brand name.

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).

Related 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 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 Principles¹⁹) would be expected to provide for use of the same drug substance name.²⁰

¹⁸ 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)).

¹⁹ The United States Pharmacopeial Convention, 2016, Guiding Principles for Coining United States Adopted Names for Drugs (2016 USP Dictionary of USAN and International Drug Names at <http://www.uspusan.com/usan/pub/index1.html>).

²⁰ 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.