Your Generics & Biosimilars Industry

Biosimilars Council
A Division of AAM

May 31, 2020

The United States Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Comments from The Association for Accessible Medicines (AAM) and the Biosimilars Council (Council) on behalf of our member companies, regarding the proposed revision to the General Notices and Requirements section of the United States Pharmacopeia (USP)—National Formulary (NF) concerning biologics nomenclature.

The Association for Accessible Medicines ("AAM"), and its Biosimilars Council ("Council") (collectively referred to in these comments as AAM), is pleased to provide input on the USP proposal to revise the process by which the name of biological medicines would be named in product monographs. USP seeks input from stakeholders impacted by the Food and Drug Administration's (FDA) March 2019 updated guidance "Nonproprietary Naming of Biological Products: Update".[1] The guidance significantly deviates from the Agency's previous 2017 guidance and applies inconsistent policy to various categories of biologics.[2]

AAM represents the manufacturers and distributors of finished generic pharmaceuticals and biosimilars, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar industry. The Biosimilars Council, a division of AAM, works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products, and educate stakeholders and patients about the safety and effectiveness of biosimilars. Member organizations include companies and stakeholder organizations working to develop biosimilar products with the intent to participate in the U.S. market.

The USP proposal largely aligns with the new biologics naming convention as described in the updated FDA guidance by providing flexibility for a biologics official title. AAM appreciates and supports stakeholders continued efforts, including USP's, to foster biosimilar competition in the interest of building a sustainable marketplace for these innovative medicines for America's patients. President Trump, Secretary Azar and former FDA Commissioner Gottlieb have all championed biosimilars as critical to the Administration's efforts to lower drug prices and reduce out of pocket costs for America's patients. Indeed, competition from FDA-approved biosimilars for costly medicines that treat many forms of cancer, rheumatoid arthritis, psoriasis, Crohn's and colitis and other conditions, stands to save the U.S. healthcare system an estimated $54 billion over ten years.[3] Biosimilars are already coming to market at an average 30% significant discount

[1] Nonproprietary Naming of Biological Products: Update, Guidance for Industry. March 2019. Available: https://www.fda.gov/media/121316/download.
[2] Nonproprietary Naming of Biological Products: Guidance for Industry. January 2017. Available: https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf.
[3] Mulcahy, Andrew W., Jakub P. Hlavka, and Spencer R. Case, Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017. https://www.rand.org/pubs/perspectives/PE264.html.

off their reference products (RP) list price and continue to heralded as key pieces of lowering prescription drug prices in the U.S.[4]

In the global regulatory marketplace, when it comes to naming of biosimilars that have met the statutory standard of having no clinically meaningful differences from its RP, both biosimilars and their RPs should share the same International Non-Proprietary Name (INN) as they do in other highly regulated markets. We do not believe a suffix to the INN - as described in the updated FDA guidance document – is necessary. AAM believes the meaningless suffix will interfere with the development of a robust biosimilars market. Moreover, alternative means for addressing FDA's stated pharmacovigilance goals currently exist that would not result in such interference.

FDA's proposal to require meaningless 4-letter suffixes to the non-proprietary names of biosimilar products and no longer require the addition of retroactive suffixes to previously approved RPs serves only to confuse patients, prescribers, pharmacists, and other healthcare professionals, while simultaneously undermining confidence in the safety and efficacy of all biologics.

Particularly troubling is FDA's proposal to add suffixes to interchangeable biologics that the Agency has deemed safe and effective to automatically substitute at the pharmacy counter. This will create a barrier to biosimilars, especially when the majority of the RPs to date will NOT have a suffix, due to the reversal of the retroactive position the Agency has taken with the updated guidance. The Agency's proposal allows for the continued spread of misinformation about the safety and efficacy of biosimilars by implying that they require an identification standard different from already approved RPs.

The FDA's updated guidance represents a serious policy misstep that puts the benefits of biosimilars at risk for America's patients. **It is misaligned with the Agency's own Biosimilars Action Plan, and the Administration's commitment to lowering drug prices for America's patients.**

While we support USP's intention, AAM continues to urge the FDA to reverse course on its current proposal for the naming of biological products, and rescind the policy, thereby removing the 'core name construct' (nonproprietary name + a suffix) and eliminating suffixes from ALL biologic products. Failure to do so puts the potential of the U.S. biologic and biosimilars market at risk.

FDA's Naming Policy Serves No Safety Purpose and Creates an Artificial Barrier to the Uptake of Biosimilars in the United States

There is a growing global consensus that the naming of RPs and their competitive biosimilar alternatives should not differ. Worldwide, biosimilars are identified by their brand name and INN and share the same INN as the RP. Most recently, both Health Canada and Australia decided to adopt a biologic naming policy that identifies all biologic medicines, including biosimilars, by their unique brand name and non-proprietary name, without the addition of a product-specific suffix.

[4] AAM Analysis of IQVIA WAC Data May 2020.

The Agency's assertion that the requirement is necessary to ensure adequate pharmacovigilance in case of an adverse event with these products is unfounded and the Agency has no data that a suffix increases pharmacovigilance. Existing naming conventions in use for the thousands of FDA-approved medicines are sufficient to address safety concerns, as evidenced by the fact that FDA will not retroactively apply the suffix requirement to marketed biologics. According to FDA's own Adverse Event Reporting System, 99% of biosimilars adverse events were reported using the product's brand name, directly contradicting FDA's stated purpose for the suffix.[5] This point was also affirmed by Dr. Janet Woodcock[6], Director of the FDA Center for Drug Evaluation and Research (CDER), and is likely due to the fact that a random 4-letter suffix is difficult to remember for patients and providers, and the brand name is most memorable.

Numerous stakeholders, including the Federal Trade Commission,[7] pharmacists, health plans, manufacturers, and consumer groups, agree that imposition of a suffix confers no safety benefit.[8] Meanwhile, the European Union, which has approved the greatest number of biosimilar medicines worldwide and has acquired more than 700 million patient days of safe and efficacious biosimilar use,[9] has not identified any difference in the "nature, severity or frequency of adverse effects between biosimilars and their reference medicine"[10] during the last 10 years. Further, the results of a European Medicines Agency pharmacovigilance study showed that 96.7% overall product identification was achieved across 10 classes of biologic products, including biosimilar medicines, sharing the same INN.[11]

FDA officials have also cited the ability to identify specific lots of biologic products as a rationale for the purpose of the suffix. All biologic medicines experience an inherent variability lot-to-lot, as the result of being manufactured in a living system. While we agree that traceability of biologic medicines from lot-to-lot is a key aspect of pharmacovigilance for these products, a random 4-letter suffix would not address this issue. Once a suffix is assigned to the product, it does not change from lot-to-lot. Therefore, the addition of the suffix does not address FDA's concern – the ability to identify the specific lot number to the product being reported.

Additionally, the majority of RPs to date do not and will not have a suffix, due to the reversal of the retroactive position the Agency has taken with the updated guidance. It is unclear how the Agency will be able to address its own concerns regarding the identity of the lot of a RP if it does not have a suffix assigned. The suffix sets-up a dual system for the Agency and all stakeholders to create, evaluate and maintain. In fact, FDA regulations already require lot and/or batch number on the label of every pharmaceutical product.[12]Additionally, a National Drug Code

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[5] Pink Sheet. "Biosimilar Suffixes Appear Superfluous In Adverse Event Reporting." Available: http://bit.ly/2ZfVn92.
[6] Pink Sheet. "Woodcock: Concerns About US FDA's Biosimilars Suffix Policy Detached From Reality." Available: http://bit.ly/2ZfGQtR.
[7] Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Available: http://bit.ly/2GhDgqo.
[8] https://www.biosimilarscouncil.org/wp-content/uploads/2019/05/FINAL-Naming-Guidance-Group-Letter-5.7.19.pdf; https://www.theamericanconsumer.org/wp-content/uploads/2019/05/Letter-to-Commissioner-Sharpless.pdf.
[9] Presentation by Adrian van den Hoven. "Biosimilar medicines clinical use: an experience based-EU perspective." Available: http://bit.ly/2Ph6aey.
[10] European Medicines Agency – European Commission: Biosimilars in the EU – Information guide for healthcare professionals, 2017. Available: http://bit.ly/2ZggS9r.
[11] A Clinician´s Guide to Biosimilars in Oncology: Understanding the Science of Extrapolation and Interchangeability. Dr. Elena Wolff-Holz. Available: http://bit.ly/2UY4DiI.
[12] 21 CFR §§ 211.130

(NDC) which is a unique set of digits that identifies the manufacturer, product, strength, dosage form and package size is required to be assigned to all approved and marketed pharmaceutical products sold in the U.S.[13]

Based on this evidence, we believe the FDA biological product naming convention requesting the inclusion of a random 4-letter suffix is arbitrary and capricious and should be abandoned altogether.

The Updated Naming Policy Undermines the "Gold-Standard" of FDA Approval

As FDA noted in the January 2017 final guidance Nonproprietary Naming of Biological Products, "Applying this [suffix] naming convention only for products licensed under section 351(k) of the PHS Act—but not for the RP 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 RPs in a clinically meaningful way or are inferior to their RPs for their approved conditions of use."[14]

As the Agency has highlighted, applying suffixes only for biosimilars and not their RPs conveys the message that the drug substance in a biosimilar differs in clinically meaningful ways from that in the RP. This is false and would consequently deter physicians from prescribing biosimilars and patients from being comfortable with biosimilars, thus impeding competition.[15] Biosimilars are approved on the basis that they have "no clinically meaningful differences" from their respective RP.[16]

FDA-approved products have other names and unique identifiers for distinct recognition including a brand name, company name, a lot number and an NDC number that readily distinguish it from other products. The Federal Trade Commission (FTC) has also weighed in several times publicly to the FDA that they believe the suffix naming convention would, and is currently, harming competition.[17]

FDA's Approach Creates Two Distinct Categories for Biologic Medicines

FDA's updated guidance suggest adding a random 4-letter suffix to newly approved biologic products and all biosimilars. The updated proposal is counter to the FDA's prior policy of adding suffixes retroactively to previously approved biologics, including those that may serve as RPs. This change results in creating two distinct naming standards for the same class of products.

FDA states that the Agency "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." However, the Agency is in fact creating a safety issue by not treating currently approved RPs the same as their

[13] 21 CFR §§ 207.33
[14] Nonproprietary Naming of Biological Products: Final Guidance for Industry. January 2017. Available: https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf.
[15] *Ibid.*
[16] 42 U.S. Code § 262.
[17] Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Available: http://bit.ly/2GhDgqo.

respective biosimilars. Although no safety concerns have been observed in highly regulated pharmaceutical markets that do not use the suffix naming convention for biologics, at present, any safety report provided to the FDA without a suffix is automatically assumed to be associated with the RP and not a biosimilar.

In addition, incorrect safety reports are more likely to occur with a random non-memorable suffix than if reporting was simply required by brand name, NDC, or any number of identifiers that are unique to each product. Incorrect attribution of a biosimilar safety report (submitted with the core non-proprietary name without the suffix) to its RP may hamper the ability to detect a safety signal with the biosimilar, which is the underlying premise of the suffix.

Additionally, FDA's policy for transitional products first approved under the Food, Drug & Cosmetic Act (FD&C) that are now under the Public Health Services Act (PHSA) directly contradicts FDA's own logic in purporting the requirement supports pharmacovigilance. For example, there are several analog insulins, including 505(b)(2) "follow-on" products, that share the same INN including 3 insulin glargine products and 2 insulin lispro products. FDA's policy would not add a suffix to the names of these products and would seemingly run counter to the reasoning for adding a suffix to other biological products for the purposes of pharmacovigilance. This is particularly contradictory because these products are not be deemed "interchangeable" under the PHSA and none are currently AB-rated for automatic substitution under the FD&C. This will cause confusion amongst patients, prescribers, pharmacists, payers, and pharmacy benefit managers, especially as future biosimilars are approved for the transitional products that share a non-proprietary name. This is counter to the FDA's stated goal of creating "a framework for safe use and optimal pharmacovigilance for biosimilar products and interchangeable products that is informed by current experience and industry best practices."[18]

FDA's updated position on implementation of the naming convention creates new pharmacovigilance issues contrary to its intended objective. It also creates inconsistency across categories of biological products where recently approved biosimilars have suffixes, and their RP and products "deemed to be license" that share a common core non-proprietary name will not. This is likely to further confuse healthcare professionals and challenge both the adoption of biosimilar and interchangeable products as well as the use of the suffix itself.

The Proposed Policy for Interchangeable Biologics Naming Puts Patient Uptake and Automatic Substitution in Jeopardy

The updated guidance also proposes to add a suffix to the non-proprietary name for interchangeable biologics. If a product is approved and marketed prior to applying and receiving the interchangeability designation, that product will retain the original suffix assigned at the time of the original approval even after gaining the interchangeable designation. This may create confusion about when a product can be substituted. For instance, a product may be on the market and not automatically substitutable at the pharmacy counter, and then later gain the interchangeable designation allowing for automatic substitution. These types of scenarios could introduce unnecessary barriers and will require re-education of healthcare professionals for specific products.

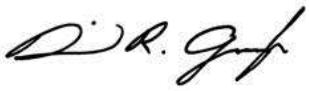
[18] Nonproprietary Naming of Biological Products: Update, Guidance for Industry. March 2019. Available: https://www.fda.gov/media/121316/download.

Further, pharmacy substitution laws vary state to state, and in some instances, a product with a different non-proprietary name than its RP cannot be automatically substituted by law or may be perceived by pharmacists to be unsuitable for substitution given the ambiguity of such laws. Elimination of the suffix concept would obviate all of these concerns related to interchangeability.

Conclusion

While we disagree with FDA's approach on biosimilars naming, we appreciate USP's efforts to minimize confusion that may result. Additionally, we encourage USP to minimize any unintended consequences that may negatively impact the public health as it works to implement its proposal. Diverse global naming schemes will create confusion and lead to unintended consequences and barriers to access for biologic and biosimilar products.

Sincerely,



David R. Gaugh, R.Ph.
Senior Vice President for Sciences and Regulatory Affairs

Your Generics & Biosimilars Industry

Biosimilars Council
A Division of AAM

Current AAM Membership List

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Glenmark Pharmaceuticals, Inc. USA
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Current Biosimilars Council Membership List

Accord Healthcare Inc.
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Lupin Pharmaceuticals
Sagent
Sandoz Inc.
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Zydus Pharmaceuticals USA

Submitted via email to JCS@usp.org

July 31, 2020

Jessica Simpson
Manager, Compendial Operations
United States Pharmacopeia

Re: Revision to PF 46(3) Official Articles of the General Notices and Requirements

Dear Ms. Simpson,

The Academy of Managed Care Pharmacy (AMCP) thanks the United States Pharmacopeia (USP) for the opportunity to submit comments in response to Revision to PF 46(3) Official Articles of the General Notices and Requirements related to monographic naming for Food and Drug Administration (FDA) approved biologics, including biosimilars.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

According to the USP notice, the March 2019 draft guidance - *Nonproprietary Naming of Biological Products: Update* indicated that the FDA no longer intends to apply an FDA-designated suffix to: (1) current and pending biological products licensed under section 351 of the PHS Act without FDA designated suffixes; and (2) transition biological products—products which will transition on March 23, 2020 from an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to a biologics license application under section 351 of the PHS Act. The draft guidance also indicated that the FDA intends to continue to apply an FDA-designated suffix to all biological products at the time they are licensed under 351(a) or 351(k).

AMCP has previously expressed concern that the establishment of a suffix will create confusion among healthcare practitioners and patients, have negative effects on the ability to ensure safe dispensing and tracking, and result in lower market adoption and cost-savings.[1] Therefore, AMCP continues to support the use of the international nonproprietary name for both biologics and biosimilars with no suffix. As an alternative, AMCP supports the use of the National Drug Code (NDC) on all claims for medications, including biologics and biosimilars. The use of NDCs along with lot number and manufacturer name provides an existing mechanism to individually identify products. AMCP recognizes the need to perform diligent pharmacovigilance for biological products post-marketing and believes this can be accomplished through the continued use of existing mechanisms such as manufacturer name, NDC, and lot numbers.

AMCP looks forward to continuing work on adoption of biosimilars with USP. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer

[1]AMCP Submitted Comments to the FDA on Updated Draft Guidance on Nonproprietary Naming of Biologics. May 2019. https://www.amcp.org/policy-advocacy/letters-statements-analysis/amcp-submitted-comments-fda-updated-draft-guidance. Accessed July 31, 2020.

USP Roundtable on Biologics Nomenclature
Remarks of Karin Bolte, Director Health Policy
American Pharmacists Association

June 23, 2020

Good morning. I am Karin Bolte, Director of Health Policy at the American Pharmacists Association (APhA). Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings.

APhA appreciates the intent of USP's proposed revisions to Section 2.20 of the Official Articles to clarify the continued application of USP public quality standards to biological products, including originator, biosimilar, interchangeable, and transition biological products such as insulin. APhA supports USP's role in setting a single standard for the quality, safety, and purity of medications. The quality benchmarks in a USP public standard allow for an independent determination that a product has been made according to quality expectations regardless of the manufacturer or manufacturing process. These standards can be – and are – used by many entities to test for quality at any point along the supply chain. As such, USP's public quality standards foster trust in the quality of biologics for the practitioners who prescribe, dispense, and administer them, as well as trust from the patients who benefit from them.

In previous comments to FDA and other federal agencies regarding biosimilar naming, APhA has consistently opposed the use of suffixes, which create confusion in the marketplace and might compromise patient safety. APhA is also concerned that FDA's application of a product-specific suffix approach to the naming of future biologics and biosimilars -- but not to previously approved biologics and transition biologics -- increases the risk of confusion and inaccurate product identification. The addition of a suffix to a biosimilar without a corresponding suffix in the name of the originator biologic gives the false impression that the biosimilar is inferior to the originator product, which can hamper the acceptance of biosimilars by both providers and patients. Additionally, APhA is concerned that there is inadequate data and experience on whether suffixes enhance pharmacovigilance, as FDA intends.

For these reasons, APhA believes that USP should not adopt FDA's naming convention in USP-NF. APhA recognizes USP's role in developing and establishing names in the United States consistent with global standards for nonproprietary naming. We recommend that USP identify originator biologics and biosimilars in the USP-NF by the same nonproprietary or core name (as defined by FDA) without the suffix. APhA also recommends that USP work with FDA and other stakeholders to implement mechanisms to enhance pharmacovigilance and to monitor for unintended consequences of naming policies, such as the use of suffixes.

Thank you for the opportunity to express APhA's views on this important issue.

July 31, 2020

Mr. Mario Sindaco
Executive Secretariat
The United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway
Rockville, MD 20852

REF: 07-20-031-A

Dear Mr. Sindaco:

This is regarding the proposed revisions to the monograph for **General Notices and Requirements, 2.20 Official Articles** that appeared as an In-Process Revision in Pharmacopeial Forum (PF), Vol. 46, No. 2. We have the following comments:

> FDA strongly encourages USP to withdraw this proposal. USP stated that these revisions are intended to "clarify the continued application of USP public quality standards to biological products, including originator, biosimilar, interchangeable, and transition biological products." We refer to our 2018-March-28 response to PF 44(1) proposal to General Notices 2.20.[1] FDA maintains our position that enforceable monographs are not beneficial for biological products. FDA continues to have significant concern that enforceable biological product monographs may impede or delay innovative technologies and may be an additional, unnecessary burden on regulated industry and FDA reviewers. FDA continues to have ongoing concerns that USP's proposal would create uncertainty for potential sponsors of proposed biosimilar or interchangeable products and could complicate licensure of a product that meets the approval requirements under section 351(k) of the Public Health Service Act, but that may not match the standards in the USP monograph associated with the reference product. Additionally, we note that the proper names for biological products licensed under the Public Health Service Act do not include the route of administration or dosage form. Thus, while USP might include this information in the title for a drug product monograph, such a designation is inconsistent with FDA's biological product nomenclature practices. As previously stated, FDA welcomes future interaction with USP on biological product related activities such as the development of optional methodological standards in general chapters that could encourage innovation and product development.

[1] Letter from Peter Marks, M.D., Director, CBER, and Janet Woodcock, M.D., Director, CDER, to Ronald T. Piervincenzi, Ph.D. (March 28, 2018), available at https://www.fda.gov/media/112103/download.

We hope these comments will be helpful to USP. Feel free to contact Jibril Abdus-Samad on my staff at Jibril.Abdus-Samad@fda.hhs.gov if there are any questions. Please use the reference number provided above on any ensuing correspondence.

Sincerely yours,

Pallavi Nithyanandan, Ph.D.
Director
Compendial Operations and Standards Staff
Office of Policy for Pharmaceutical Quality
Center for Drug Evaluation & Research

July 30, 2020

Jaap Venema, Ph.D.
Chief Science Officer & Chair, Council of Experts
Anthony Lakavage, J.D
Senior Vice President, Global External Affairs & Secretary, USP Convention
United States Pharmacopeia
12601 Twinbrook Parkway
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Re: USP March 2020 Compendial Notice Regarding Biologics Nomenclature

Dear Mr. Venema and Mr. Lakavage:

In March 2020, USP published a Compendial Notice to solicit stakeholder feedback on a USP proposal regarding biologics nomenclature, which is intended to clarify the continued application of USP standards to biological products, including originator, biosimilar, and transition biological products licensed under the Public Health Service Act. The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) are pleased to share our perspectives in response to USP's solicitation of feedback. Specifically, we continue to encourage USP to support policies that facilitate the development of more affordable biosimilars, including insulin products, and that promote confidence in these biological alternatives.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

NCPA represents America's community pharmacists, including over 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care settings. Together, our members represent a $76 billion healthcare marketplace, employ 250,000 individuals, and provide pharmacy services to millions of patients every day. To learn more, visit www.ncpa.org.

Naming policies for biological and biosimilar drugs have significant patient safety implications and are therefore of critical importance to the pharmacy community. We support naming policies for biosimilar drugs and biologics that are consistent with the naming conventions for brand and generic small molecule drugs. This naming approach is familiar to healthcare providers and patients alike.

We have concerns with any naming scheme for biological and biosimilar products that deviates from traditional naming practices, as this can lead to general confusion relative to the appropriate use, safety, and efficacy of these medications, as well as therapeutic duplication that would be detrimental to patients' health. Moreover, special naming practices for biological and biosimilar products can undermine healthcare provider and patient confidence in biosimilars and perpetuate the notion that biosimilars are not comparable to the innovator biologic.

When commenting to the Food and Drug Administration (FDA) in response to the Agency's proposed biological product naming scheme outlined in the Draft Guidance on Nonproprietary Naming of Biological Products (August 2015), USP expressed concerns with the creation of a special naming scheme for biological products, noting that product "[n]ames must be useful, simple, concise, and devoid of nonsensical information to allow them to be easily read and understood by practitioners and minimize the potential for medication errors." We strongly agree with this USP recommendation.

We further agree that standardization between USP's and FDA's biological product naming practices is important. However, we encourage USP not to yield to FDA's naming scheme for biological and biosimilar products. Notably, FDA's rationale for the naming approach is to facilitate pharmacovigilance for biological and biosimilar products. Given the confusion the new naming scheme creates, this is not the appropriate way for FDA to address its pharmacovigilance concerns.

Turning to the specifics of the USP proposal, as USP recognized during your June 23 Roundtable on Biologics Nomenclature, this proposal is particularly important for transition products,[1] as it would set up two different naming schemes for biologics, evidenced by the fact that transition products would not be subject to the more recent FDA naming scheme that utilizes a suffix.

We agree that transition products should follow their existing nomenclature that does not utilize a suffix, and which is consistent with FDA's naming practices for small molecule drugs. One of the best and clearest ways we can cultivate confidence in biosimilar and interchangeable products and their reference products and communicate the relationship between these medications is through naming practices. With this in mind, we believe that FDA should apply this nomenclature to all biologics and biosimilars. All biosimilars, not only transition products, should share the same nonproprietary name as their reference products. Over the years, physicians and patients have come to understand that a shared nonproprietary name denotes that a generic product is at least comparable to the brand. Deviating from this naming convention perpetuates the notion that biosimilars are not substantially comparable to the innovator biologic. We therefore encourage USP to leverage its patient safety expertise and work with FDA to develop a more appropriate approach for biological and biosimilar product pharmacovigilance rather than adopt a standard that provides support for FDA's misguided naming practices for biological and biosimilar products.

[1] The USP slide deck, slide 9, for the Roundtable acknowledges that the "[p]roposal is particularly important for medicines that transitioned from an approved application under section 505 of the FDCA to a biologics license application under section 351 of the PHS Act (transitioned on March 23, 2020)."

We thank USP for the opportunity to communicate our perspectives related to biological product nomenclature. Given the potential patient safety implications, we appreciate USP considering our comments on this important policy matter.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy and Government Affairs Operations
National Community Pharmacists Association

Kevin N. Nicholson, R.Ph., J.D.
Vice President, Public Policy and Regulatory Affairs
National Association of Chain Drug Stores

July 17, 2020

Ms. Jessica Simpson
Manager, Compendial Operations
United States Pharmacopeia (USP)
Submitted via https://www.uspnf.com/pharmacopeial-forum

Re: Revision to Section 2.20 Official Articles of the General Notices and Requirements

Dear Ms. Simpson:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, ANSI-Accredited Standards Developer (ASD) consisting of more than 1700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years, NCPDP has been committed to furthering the interoperable electronic exchange of information among a wide array of healthcare stakeholders. To assist in consistent and accurate identification of drugs and health-related products within NCPDP's stated mission, NCPDP's Work Group 2 Product Identification deals with product identification systems and any type of descriptive data, including naming, that serves to uniquely identify a product with the intent of establishing standards for product identification to avoid ambiguity in distinguishing one product from another.

The product information exchange procedures developed and maintained by NCPDP are used by all originator biologics and biosimilars licensed in the US to date, and it is anticipated they will also be used for all originator biologics, biosimilars, and interchangeable biologics in the future. As such, NCPDP is central to developing standards by which these products are distributed and recorded, including identification of products for the purpose of pharmacovigilance.

NCPDP appreciates this opportunity to provide additional comments on the revision to Section 2.20 Official Articles of the General Notices and Requirements. Please refer to NCPDP's original comments submitted to you on March 29, 2018, which continue to represent NCPDP's position opposing the addition of prefixes and/or suffixes to the nonproprietary ("core") (i.e., United States Adopted Names [USANs], International Nonproprietary Names [INNs]) names of biologics.

In response to the current revision proposal, NCPDP submits the following alternative wording for USP's consideration:

Revise Section 2.20 Official Articles to add the following language at the end of the second paragraph:

"For a biologic licensed under the Public Health Service Act, the *official title* shall be the title specified in the relevant monograph. Names used by the US Food and Drug Administration (FDA) may differ from the official USP-NF title by modifying the United States Adopted Name (USAN) (defined by FDA as the "core" name) with a prefix and/or suffix to create an FDA-designated "proper" name, but such modifications are informational only and not part of the official monograph title…"

The rationale for NCPDP's alternative wording follows.

NCPDP continues to disagree with the need for biologics prefixes and suffixes in Nonproprietary Names (NPNs): NCPDP continues to oppose ongoing efforts by the FDA that impose the inconsistent addition of prefixes and/or suffixes to the core names of certain biologics (including biosimilars), believing this practice is both unnecessary and unproven to substantively increase the accuracy of product-specific pharmacovigilance. Improved pharmacovigilance is FDA's unsubstantiated principal claim for the need to modify core names, and we continue to invite data as evidence to indicate the contrary. In fact, NCPDP's opposition has been further supported by the resultant confusion that already has occurred. Contrary to the FDA's assertions, electronic drug information and standards organizations as well as many associated industry sectors (e.g., prescribers, dispensers, prescription processors, drug knowledge bases) faced with implementing and interpreting this prefix/suffix NPN policy believe the altered naming policy will lead to even greater confusion in pharmacovigilance.

As a result, NCPDP also continues to strongly oppose USP's proposal to align its own naming conventions for biologics with those of FDA on this issue.

USP is proposing to revise the General Notices and Requirements (GN) section of the United States Pharmacopeia—National Formulary (USP-NF) to ensure alignment between FDA biologics nonproprietary naming convention and USP's compendial naming approach. The USP proposal would accommodate the revised biologics naming convention proposed by the FDA, which would add a meaningless prefix and/or suffix to the nonproprietary name. NCPDP understands USP's rationale for proposing to align its naming practices with those of FDA in order to reduce confusion among pharmacists, other healthcare providers, manufacturers and other stakeholders, and allow USP monographs and reference standards to continue to apply. However, FDA's policy already has caused considerable confusion and adverse downstream stakeholder consequences and has not been established scientifically to improve pharmacovigilance. Such confusion can only be expected to increase as the use of suffixes and prefixes expands, especially as they continue to be inconsistently applied. Therefore, because NCPDP remains strongly opposed to FDA's naming convention for biologics, we must also oppose USP's proposed alignment with it.

Substantial opposition in public comments to USP on its proposal: NCPDP is surprised by USP's decision to move forward in aligning with FDA's biologics naming convention since all but two comments received by USP in response to the original September 2017 proposal for change in Section 2.20 opposed it and one of the commenters supporting it was FDA itself (https://www.usp.org/sites/default/files/usp/document/our-work/biologics/usp-stakeholder-

comments-biologics-nomenclature.pdf). We recognize that USP is not endorsing the use of prefixes and/or suffixes in nonproprietary naming of drugs and biologics. However, we remain concerned that the proposed revision to Section 2.20 may be interpreted incorrectly to implicitly support FDA's deviation from standard international naming practices for biologics.

In fact, it is notable that even the pharmaceutical industry's largest and most influential trade association—the Pharmaceutical Research and Manufacturers of America (PhRMA)—opposed USP's proposal stating that "the proposed change is unnecessary to achieve USP's intended goals and would cause confusion that could create a public health risk."

Absence of data to support the new biologics naming convention: Central to NCPDP's continued opposition to, and grave concern about, the addition of prefixes and/or suffixes to the USAN/INN is the complete absence of publicly accessible data supporting the contention that pharmacovigilance is enhanced by use of FDA's unique biologics naming convention. This convention is based entirely on hypothetical concerns and conjectures about how the proposed system will be used. We are not aware of any well-designed quantitative or qualitative studies supporting FDA's biologics naming policy as a superior means for enhancing pharmacovigilance. To the contrary, factual evidence from adverse drug event reports in both the US and Canada has shown that reporting is almost exclusively by brand name and has been largely successful in achieving accurate product-level attribution of spontaneously reported adverse effects for suspected biologics.

At its core, USP is a science-based standards development organization and therefore should have demanded FDA provide compelling evidence of superiority for its biologics naming convention from a pharmacovigilance perspective before accommodating the same naming convention in USP-NF. If FDA has compelling evidence from well-designed studies, FDA should be transparent and make the evidence and studies publicly accessible for review by experts in the field, including USP. Without such evidence, USP is simply acquiescing to FDA's unjustified opinion, and one that is not without risks that must also be considered.

In addition, NCPDP sees no essential need for FDA to continue pursuing introduction of prefixes and/or suffixes or any other unique naming forms for biologics since other, more effective means than nonproprietary names currently exist in the US for distinguishing biosimilar products (e.g., national drug codes [NDCs], track and trace regulations, the standardized numerical identifier [SNI], global trade item number [GTIN], other product identifiers, and brand names themselves).

FDA's biologics naming convention is very different from that proposed by the World Health Organization: NCPDP is further surprised with USP's decision to align with FDA's biologics naming policy since it runs counter to the rest of the world and the Pharmacopeia's emphasis on the need for global harmony in all nonproprietary naming, including biologics. As USP has noted, global alignment of the biologics naming convention would greatly assist in biosimilar acceptance that in turn would lead to an increase in patient access. While WHO did consider suffixes for those countries that lack brand names, their so-called biologics qualifier initiative was subsequently rejected. And it is notable that, even were it to have been pursued, it did not alter the nonproprietary name *per se*. Even FDA itself concurred with the established nonproprietary naming system, in their letter to WHO, September 1, 2006, entitled *U.S. FDA Considerations: Discussion by National Regulatory Authorities with World Health Organization (WHO) On Possible*

International Non-proprietary Name (INN) Policies for Biosimilars (attached as an appendix as it is no longer readily accessible at FDA.gov). A proliferation of biologics naming conventions will slow uptake, limit access, and result in worldwide confusion and confounded pharmacovigilance accuracy.

NCPDP's recommended alternative wording for section 2.20 revision: As a result of these concerns and to provide some needed clarification of naming differences that may exist between official USP monograph titles and FDA names for certain biologics, NCPDP proposes the following alternative wording for USP's consideration (also stated above in introductory comments):

> Revise Section 2.20 Official Articles to add the following language at the end of the second paragraph:
>
> "For a biologic licensed under the Public Health Service Act, the *official title* shall be the title specified in the relevant monograph. Names used by the US Food and Drug Administration (FDA) may differ from the official USP-NF title by modifying the United States Adopted Name (USAN) (defined by FDA as the "core" name) with a prefix and/or suffix to create an FDA-designated "proper" name, but such modifications are informational only and not part of the official monograph title…"

USP states in the *Pharmacopeial Forum (PF)* Briefing on this proposed change that, "it will not publish as official any new product-specific monographs for biologicals unless they have FDA and stakeholder support," and states further that, "FDA no longer intends to apply an FDA-designated suffix to: (1) current and pending biological products licensed under section 351 of the PHS ACT without FDA-designated suffixes; and (2) transition biological products—products which transition on March 23, 2020 from an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to a biologics license under section 351 of the PHS Act." (https://online.usppf.com/usppf/document/GUID-6E790F63-0496-4C20-AF21-E7C283E3343E_60101_en-US)

Finally, it is curious that despite FDA's position on biologics naming, a new insulin glargine product Semglee® that references Sanofi's Lantus® recently (June 11, 2020) was approved by FDA but does not include a suffix modifier. While the product was submitted under the generic 505(b)(2) New Drug Application pathway, it automatically is deemed a biologic under section 351(a) of the Public Health Service Act of the Biologics Price Competition and Innovation Act (BPCIA), based on a policy enacted March 23, 2020. This FDA action of not applying a suffix becomes all the more notable since the manufacturer already has announced its intent to pursue an interchangeability designation for this product. It also raises questions about FDA's intent on requiring suffixes and/or prefixes to the nonproprietary names for other yet-to-be-approved biologics that contain matching active moieties or reference those products that were rolled-over.

NCPDP's proposed wording change acknowledges the existence of naming aberrations imposed by FDA, while still maintaining international harmonization of biologics naming by USP and avoids placing USP's imprimatur on a naming approach that has not been shown to date to be scientifically based. It also addresses USP's goal of avoiding an interpretation of misbranding for FDA-imposed biologics names that include a prefix and/or suffix and thus do not agree with official USP titles.

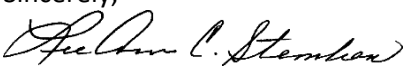
In addition, USP's proposed alignment with FDA biologics naming convention will weaken pharmacovigilance. FDA biologics naming convention is already increasing the cost and complexity of the US healthcare system and will ultimately lessen confidence in and access to biosimilars. Given all these reasons, we do not support the revisions proposed by the USP and we urge the USP to reconsider its position and consider instead wording proposed by NCPDP.

Thank you for your consideration of our input.

For direct inquiries or questions related to this letter, please contact:

Terry Fortin
Assistant Senior Manager, Standards Development
NCPDP
E: standards@ncpdp.org

Sincerely,



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31 July 2020

Jessica Simpson
Manager, Compendial Operations
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville MD 20852

Re: General Notices revision proposed in *Pharmacopeial Forum* 46(2)

Dear Ms. Simpson:

PDA appreciates the opportunity to comment on the revision to the General Notices proposed in *Pharmacopeial Forum* [*PF*] 46(2), which would add a sentence regarding biologics nomenclature and official titles. We understand that USP published this proposal for a second time to gain updated comments and feedback on this difficult nomenclature topic.

As you know, biologics nomenclature is complex. USP's decisions, while focused on US regulatory policy, would impact products manufactured and marketed around the globe. Because nomenclature affects supply, USP's language in the *General Notices* may impact patient access to important medicines worldwide.

PDA encourages USP to pause use of the *PF*'s formal notice and comment process to advance this issue and to provide clear messages about USP's overall goals and intentions. This would begin a conversation focused on finding answers. USP's conversation with stakeholders could thoroughly consider all the issues involved, including global harmonization.

PDA would be happy to serve as a facilitator for this conversation. Because PDA has not expressed any views on USP's proposed policy, we can help guide the conversation in a thoughtful and productive manner. As a neutral party seeking only continued patient access to high quality products, PDA can convene and guide a workshop or conference of originator and biosimilar manufacturers, regulators, and USP. PDA feels confident that such a conversation would reach a satisfactory result.

Finally, we support USP's continued focus, as expressed in the Briefing, "on developing performance standards, which are applicable to classes of biologics (e.g., monoclonal antibodies or cell therapies), as well as standards for raw materials," rather than monographs. As the Briefing notes, USP has received non-aligned feedback from key stakeholders regarding the development of monographs for biological products. Test methods for quality attributes, in contrast, provide meaningful value to patients and to manufacturers. PDA would be pleased to continue to engage with you in scientific dialogue on standards that would be most helpful and advance our common goals of promoting access to and protecting the quality of biological products.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments have been prepared by PDA

members with expertise in pharmaceutical, biopharmaceutical, and combination products manufacturing and compendial topics on behalf of PDA's Regulatory Affairs and Quality Advisory Board and Board of Directors.

If you have any questions, please do not hesitate to contact me via email at johnson@pda.org.

Sincerely,

Richard Johnson
President and CEO

cc: Glenn Wright, PDA; Ruth Miller, PDA

July 31, 2020

Ms. Jessica Simpson
Manager, Compendial Operations
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JCS@usp.org

Re: Comments on Notice of Intent to Revise Section 2.20 of the Official Articles of the General Notices and Requirements

Dear Ms. Simpson:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments on the United States Pharmacopoeial Convention's (USP's) *Pharmacopeial Forum (PF) 46(2)* (Proposed Revision).[1] PhRMA previously submitted comments to USP on the associated 2017 Notice of Intent to Revise.[2]

PhRMA represents the country's leading innovative biopharmaceutical research and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone.

In the Proposed Revision, USP proposes to amend the second paragraph of Section 2.20 of the Official Articles of the General Notices and Requirements by adding the text underlined below:

> The title specified in a monograph is the *official title* for such article. Other names considered to be synonyms of the official titles may not be used as substitutes for official titles. For a biologic product licensed under the Public Health Service Act, the official title shall be the title specified in the relevant monograph plus any prefix and/or suffix designated by the FDA unless otherwise specified in the applicable monograph.

USP explains in the Proposed Revision that the "revision will clarify the continued application of USP public quality standards to biological products, including originator, biosimilar, interchangeable, and transition biological products . . . . The revision will help ensure that a biological product that is given an FDA-designated prefix and/or suffix has an applicable USP quality standard."

Consistent with our prior comments, PhRMA urges USP to retain Section 2.20 in its present form because the proposed revision is still unnecessary to achieve USP's intended goal and would cause confusion that could create a public health risk.[3] First, as before, the proposed change is not needed to ensure consistency between USP and FDA in the naming of biological products, particularly in light of FDA's approach to identifying the "established name" of such products. Second, the proposed revision could still cause confusion as to which biological

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[1] USP, *Pharmacopeial Forum (PF) 46(2)*.
[2] *See* PhRMA, Comments on Notice of Intent to Revise Section 2.20 of the Official Articles of the General Notices and Requirements (Nov. 3, 2017).
[3] *Id.*

products comply with a monograph.

I. The Proposed Revision Is Not Necessary to Ensure Consistency Between USP and FDA in the Naming of Biological Products.

The proposed revision is not needed to ensure consistency between USP and FDA in the naming of biological products because FDA already has taken steps to harmonize the agency's approach with USP procedures.[4] Specifically, FDA has adopted an approach to identifying the "established name" of a biological product that takes into account any applicable "official title" and the agency's use of distinguishing suffixes in the nonproprietary names of biological products.[5] Indeed, FDA elaborated on these points in comments to USP on the 2017 Notice of Intent to Revise, observing that USP's proposal would, rather than ensure consistency, "present an additional, unnecessary burden on regulated industry."[6] PhRMA agrees with FDA and "strongly encourages USP to withdraw its proposal."[7]

FDA addressed similar issues in a 2017 citizen petition response. There, FDA explained how the agency believes its approach to the nonproprietary naming of biological products accords with applicable statutory and regulatory provisions.[8] Under one such provision—section 502(e) of the Federal Food, Drug, and Cosmetic Act (FDCA)—a drug is deemed to be misbranded unless its label bears, among other things, the "established name . . . of the drug, if there is such a name."[9] "Established name" is defined as:

> (A) the applicable official name designated pursuant to [FDCA] section 508, or
> (B) if there is no such name and such drug . . . is an article

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[4] In the highly similar 2017 Notice of Intent to Revise, USP explained that the changes are intended to accomplish the following goals:

1. "[E]nsure consistency between USP and FDA in the naming of biological products,"
2. "[H]elp address any potential compliance issues by ensuring that a biologic product that is given an FDA-designated suffix is not out of compliance with an applicable USP monograph," and
3. "[M]aking it possible to apply different compendial approaches in situations where products share the same core name but have different suffixes

See, USP, *Notice of Intent to Revise* (posted Sept. 29, 2017; updated Oct. 5, 2017) (Notice of Intent to Revise), http://www.uspnf.com/notices/general-notices-requirements (last visited June 25, 2020).

[5] Under FDA's 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." *See* FDA, Guidance for Industry, *Nonproprietary Naming of Biological Products*, at 1 (Jan. 2017) (emphases omitted).

[6] *See* FDA, Letter from Peter Marks, M.D., and Janet Woodcock, M.D., to Ronald Piervincenzi, PhD (Mar. 28, 2018), available at https://www.fda.gov/media/112103/download. (FDA 2018 Comments)

[7] *See id*. At 3.

[8] *See* FDA, Letter from Janet Woodcock, M.D., and Peter Marks, M.D., Ph.D., FDA, to Chester Davis, Jr., Generic Pharm. Ass'n, et al., re: Docket Nos. FDA-2013-P-1153, FDA-2013-P-1398, and FDA-2014-P-0077 (Jan. 19, 2017) (Citizen Petition Response), at 8-10.

[9] FDCA § 502(e)(1)(A)(i).

> recognized in an official compendium, then the official title thereof in such compendium, or
> (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug."[10]

FDA explained that the "official title" specified in a USP monograph would constitute the established name of a biological product, under clause (B) quoted above, only if, at the time of approval, "FDA designates a proper name in the license for the biological product that matches the official title of the relevant USP monograph, and the biological product otherwise meets the identity and definition set forth in that monograph."[11]

If, instead, "FDA assigns a proper name to the biological product that differs from the monograph's official title—for example, because the proper name features a suffix and the official title does not—the product would not be 'an article recognized' in a USP monograph within the meaning of section 502(e)(3)(B)," so the official title would not supply the established name.[12] Rather, the product's "common or usual" name would serve as the established name.[13] The common or usual name would be the proper name assigned by FDA in the product's license and would include the core name plus a distinguishing suffix under FDA's naming convention.[14] Because the FDA-assigned proper name would be the product's established name, the use of that proper name on the product's label would comply with section 502(e)(1) of the FDCA, so the product would not be deemed misbranded.

Moreover, to the extent USP's proposal is targeted at transition biological products, FDA's policy – announced in draft guidance following the 2017 Notice of Intent to Revise – moots this rationale. Specifically, FDA announced in 2019 that the Agency "does not intend to apply [suffixes] to the proper names of transition biological products."[15] Accordingly, to the extent a USP monograph exists for the proper name of a transition biological product, the monograph will continue to apply, as FDA does not intend to add a suffix to these transition products.

As summarized, FDA already has achieved consistency between the USP and FDA as to the nonproprietary naming of biological products. In particular, FDA has explained that the FDA- assigned proper name will be the established name if a biological product is approved with an FDA-designated suffix that is not included in the official title. Because FDA has reconciled its new naming convention with USP procedures, there is no need for USP to revise Section 2.20. Moreover, to the extent USP's proposal is targeted at transition biological products, FDA's stated policy of not applying suffixes to the proper name of such transition products moots this purported rationale.

II. The Proposed Revision Could Cause Confusion as to Whether a Biological Product Complies with a USP Monograph.

Also, the proposed revision could lead to confusion as to whether a biological product

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[10] *Id.* § 502(e)(3).
[11] *See* Citizen Petition Response, at 9-10.
[12] *Id.* at 10.
[13] *Id.*
[14] *Id.*
[15] *See* FDA, Draft Guidance for Industry, Nonproprietary Naming of Biological Products: Update at 5 (Mar. 2019).

complies with a USP monograph. A biological product might not meet the specifications of a monograph that was developed using a different product with the same core name due to, for example, differences between a reference product and biosimilar product. A biosimilar product may be approved notwithstanding "minor differences" from the reference product "in clinically inactive components" and differences that are not "clinically meaningful . . . in terms of the safety, purity, and potency of the product."[12] But the proposed revision would create the impression that all products sharing the same core name comply with that monograph, by extending the official title of a monograph to cover all products sharing the same core name "unless otherwise specified in the applicable monograph."[13] In practice, the monograph might not be amended to expressly exclude a biosimilar or other biological product before its approval, and it is unclear whether any existing monographs need to be revised to state that they do not cover specific biological products that currently are licensed. Accordingly, there is a significant risk that the proposed revision would suggest that a product that was not the basis for the development of the monograph complies with a USP monograph when it does not, if the monograph has not yet been revised to reflect that fact. PhRMA recommends that USP not adopt the proposed revision to prevent this risk of confusion.

III. Conclusion

PhRMA appreciates USP's consideration of these comments. We would welcome the opportunity to discuss any of these points further.

Sincerely,

/s/
David E. Korn
Vice President, Intellectual Property and Law

/s/
Lucy Vereshchagina, PhD
Vice President, Science and Regulatory Advocacy