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By Electronic Submission

Division of Dockets Management (HFA-305),
Food and Drug Administration, 5630 Fishers
Lane, rm. 1061, Rockville, MD 20852

Comments on Draft Guidance for Industry Nonproprietary Naming of Biological Products: Update [Docket No. FDA–2013-D-1543]

Dear Madam/Sir:

Pfizer Inc (Pfizer) is submitting these comments in response to the Federal Register notice of March 08, 2019 (84 FR 8534) on the Draft Guidance for Industry: *Nonproprietary Naming of Biological Products: Update (*"Draft Guidance"*)*.

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products. From specialized efforts in biosimilars and rare disease to oncology and vaccines, we are committed to developing medical solutions that will matter most to the people we serve.

Pfizer appreciates the information provided in the Draft Guidance to update stakeholders as to FDA's current thinking on nonproprietary names of biological products licensed under section 351 of the PHS Act that do not include an FDA-designated suffix. Pfizer's general comments on FDA's proposed updates to the Naming Guidance[1] are outlined below for consideration.

GENERAL COMMENTS:

A. Biological Products Licensed Without a Suffix and Transition Biological Products – Pharmacovigilance Considerations

The Draft Guidance states FDA no longer intends to modify the proper names of biological products that were licensed under the PHS Act without an FDA-designated suffix in their proper names. FDA believes that applying the naming convention to biological products, including biosimilars, at the time they are licensed without applying it to licensed reference biological products that do not contain a suffix in their proper names would accomplish the core objective of pharmacovigilance and safe use. Experience with generic drugs

[1] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf

demonstrates that despite drastically reduced dispensing of branded drugs following entry of generic options to the marketplace, there is a substantial increase in adverse event reports being ascribed to the branded product. This suggests that adverse events associated with the generic drug are being inappropriately attributed to the brand. In the event of a quality-associated issue, this could result in a quality issue remaining undetected. In order for the proposed naming convention to prevent this kind of inaccurate reporting for biological products the suffix would have to be consistently utilized in pharmacovigilance reporting. Based on experience to date, the suffix is rarely included in adverse event reports[2]. Pfizer believes that application of the naming convention to both biosimilars and their reference products may increase the likelihood of awareness and utilization of the suffixes in adverse event reporting.

Pfizer appreciates that retroactively imposing the naming convention on all biological products licensed under the PHS Act would be a burden to sponsors and the healthcare systems; as such, Pfizer recommends that the naming convention be retroactively applied only to innovator biologics that serve as reference products for a biosimilar. Further, the Agency should be flexible regarding the amount/length of time innovator biologics manufacturers/companies would have to retroactively implement the convention in order to ensure such manufacturers/companies can develop processes and implement the new convention efficiently; and, without disrupting supply or impacting pharmacovigilance.

Pfizer recognizes that because biosimilars are never exact copies of the innovator medicine, establishing appropriate standards for biosimilarity remains an important area for scientific, legislative and regulatory debate. Pfizer supports the notion that biosimilars should have names readily distinguishable from the reference product and agrees that a distinguishable name will be necessary to track adverse events related to an individual product and to ensure appropriate prescribing and dispensing. However, based on data to date on pharmacovigilance reporting for licensed biosimilars, the suffixes are not being consistently utilized, bringing in to question whether the FDA's recommendations are the best path forward to meet the objectives described. The long-term benefits of transparency in prescribing and improved pharmacovigilance outweigh the need to manage potential short-term issues associated with implementation of the new naming convention.

B. Biological Products Licensed Without a Suffix and Transition Biological Products – Market Uptake Considerations

In enacting the BPCIA, Congress intended to help reduce healthcare costs by enhancing patient access to additional biological treatment options. FDA has engaged in various initiatives aimed at encouraging and facilitating the development and approval of biosimilars. Despite these continued efforts, significant biosimilar cost savings have yet to be realized due to slower than expected development, approval, acceptance, and thus availability of biosimilars in the U.S. market. Pfizer believes that a contributing factor to this slow uptake is a lack of market confidence in biosimilars that results from, among other things, the efforts of certain reference product sponsors to disseminate false and misleading information that casts doubt about the safety and efficacy of biosimilars in the minds of patients and

[2] Derrick Gingery. Biosimilar Suffixes Appear Superfluous In Adverse Event Reporting. Pink Sheet 10 Oct 2018. https://pink.pharmaintelligence.informa.com/PS124042/Biosimilar-Suffixes-Appear-Superfluous-In-Adverse-Event-Reporting

prescribers.[3] The Draft Guidance states that applying the naming convention to all biological products at the time they are licensed under 351(a) or 351(k) is expected to mitigate the risk of inaccurate perceptions of the relative safety and effectiveness of biological products based on licensure pathway. Pfizer is concerned that application of the naming paradigm to biosimilar and interchangeable biological products but not their reference products, with the stated objective of pharmacovigilance and safe use, creates a perceived difference and disingenuous exploitation of this perception could undermine the biosimilars pathway.

Pfizer is also concerned that failure to apply the naming convention to reference biological products that were licensed without an FDA-designated suffix in their proper names could have unintended consequences on market uptake due to prescribing practices. Inability to recall or recognize suffixes associated with biosimilar products may lead to situations where a physician prescribes a product utilizing the INN without the suffix even if the intention was to prescribe a biosimilar. In the absence of an interchangeability designation the reference product would likely be dispensed. Application of the naming convention more broadly to reference biological products may further facilitate appropriate dispensing and is an important step towards maximizing the success of biosimilar and interchangeable biological products.

Pfizer considers that retrospective application of the naming convention to innovator biologics that serve as reference products for a biosimilar would help mitigate some of these market uptake considerations.

C. Suffix Format Considerations

If FDA maintains its policy to require a unique identifier/suffix, as Pfizer has noted in previous comments[4], Pfizer believes the four-letter suffix should be meaningful and somehow derived from – or in some way related to – the name of the license holder or the entity responsible for pharmacovigilance[5]. Pfizer recommends that the suffix for a biological product be unique to each license holder[5] and shared by each biological product in that license holder's portfolio. A single, *meaningful* suffix that is related to the name of the responsible entity would be more easily recognizable to health care professionals and other adverse event (AE) reporters, lend familiarity to providers and those inputting data, and increase the likelihood that the suffix is accurately and consistently provided in safety reporting. Appropriate identification of the dispensed product is essential to ensure safe use of biological products and effective pharmacovigilance. Pfizer believes that the advantages of a single, meaningful suffix derived from – or related to – the name of the license holder[5] would better achieve FDA's stated pharmacovigilance goals than a randomly assigned, meaningless four-letter suffix.

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[3] Citizen Petition from Pfizer Inc. Aug 2018. Docket No. FDA-2018-P-3281. https://www.regulations.gov/docket?D=FDA-2018-P-3281

[4] Comment from Pfizer. Oct 2015. Docket No. FDA-2013-D-1543. https://www.regulations.gov/document?D=FDA-2013-D-1543-0151

[5] Pfizer considers the term "license holder" could also refer to the entity responsible for pharmacovigilance, if different from the license holder.

D. Transitional Biological Products

The Draft Guidance states, FDA also does not intend to apply the naming convention to the proper names of transition biological products. For demonstration, there are four chorionic gonadotropin products, only two of which have proprietary names.[6] FDA has noted in public statements that proprietary names can help mitigate the lack of a suffix, but in these cases there are transition products being marketed without proprietary names. It is unclear how FDA made the determination that unique nonproprietary names were necessary for biosimilars and prospectively approved biological products, but not transitioning biological products. Further, the burden on transitional biological product sponsors to implement this change would be minimized given the holder of a deemed BLA will need to revise the product labeling to conform to labeling requirements for biological products regulated under section 351 of the PHS Act.[7] Suffix implementation could be planned to coincide with other necessary labeling and packaging changes incurred due to the transition.

E. Vaccines

Pfizer considers the currently available identification systems associated with the administration of vaccines sufficiently robust to ensure safe dispensing practices and optimal pharmacovigilance. In addition, vaccine names are often abbreviated in a hyphenated string of letters and addition of the four-letter suffix naming convention to vaccines risks causing confusion that the suffix relates to an attribute of the product rather than a distinguishing name; this is particularly true given the random nature of the suffixes. As such, Pfizer supports removal of vaccines from the scope of the naming convention described in the Naming Guidance.

CONCLUSION:

Pfizer believes FDA should apply the naming convention to both biosimilars and their reference products. Broader application will increase the likelihood of awareness and utilization of the suffixes in adverse event reporting and prescribing practices and mitigate the risk of inaccurate perceptions of the relative safety and effectiveness of biological products based on licensure pathway. Pfizer also urges FDA to reconsider the use of a single, meaningful suffix derived from or related to the name of the license holder as such a meaningful suffix is more likely to achieve our shared goal of tracking adverse events related to an individual product and ensuring appropriate prescribing and dispensing. Finally, Pfizer supports removal of vaccines from the scope of the naming convention

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[6] Preliminary List of Approved NDAs for Biological Products That Will Be Deemed to be BLAs on March 23, 2020.
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM628117.pdf?utm_campaign=FDA%20issues%20two%20guidances%20and%20other%20documents%20related%20to%20the%20deemed%20to%20be%20a%20license&utm_medium=email&utm_source=Eloqua

[7] Draft Guidance for Industry on The "Deemed to be a License" Provision of the BPCI Act Questions and Answers. 2019.
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM628115.pdf?utm_campaign=FDA%20issues%20two%20guidances%20and%20other%20documents%20related%20to%20the%20deemed%20to%20be%20a%20license&utm_medium=email&utm_source=Eloqua

described in the Naming Guidance. We appreciate the opportunity to comment on this Draft Guidance. If you have any questions about these comments, please contact Laura McKinley at laura.m.mckinley@pfizer.com.

Sincerely,

Laura McKinley

Laura McKinley, Ph.D.
Director, Regulatory Policy