September 21, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852
Submitted VIA ELECTRONIC SUBMISSION at www.regulations.gov

RE: Docket No. FDA-2018-N-2689 Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments

Dear Sir or Madam,

The National Council for Prescription Drug Programs (NCPDP) submits this letter to the Agency in response to a request for comments on ways to balance development of biosimilars and interchangeable biologics with innovation of new therapeutic proteins.

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of more than 1,400 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system. Through a consensus building process in collaboration with other industry organizations, our members develop these solutions to improve safety, privacy and healthcare outcomes for patients and healthcare consumers, while reducing costs in the system.

For over 40 years NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. To assist in consistent and accurate billing of pharmaceutical products, NCPDP developed the Billing Unit Standard (BUS) that is widely adhered to throughout the pharmacy industry. The BUS is maintained by the NCPDP Work Group 2 Product Identification that deals with issues relating to the identification of drugs and health related products within NCPDP's stated mission. Identification consists of how the product is billed (billing units, quantity designations), product identification systems, and any type of descriptive data which serves to uniquely identify a product with the intent to establish standards for product identification such that there is no 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 that 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 has already commented that in our opinion, biosimilars and interchangeable biologics should carry the same non-proprietary names as their respective reference products. We incorporate by reference our submission of August 20, 2012 to Commissioner Hamburg in which we stated that the INN "should not be redesigned to respond to concerns about pharmacovigilance and drug tracking."

We reiterated this position in comments submitted in support of Generic Pharmaceutical Association, Citizen Petition 17SEP13 (Docket # FDA-2013-P-1153) and Novartis, Citizen Petition 28OCT13 (Docket # FDA-2013-P-1398). We incorporate by reference those comments in this submission.

We also incorporate by reference our comment letter of February 7, 2017 submitted to OMB Control No. 0910-New, "Nonproprietary Naming of Biological Products" (Docket No. FDA-2013-D-1543) in response to the FDA's January 2017 Guidance "Nonproprietary Naming of Biological Products." These comments expressed to the Agency for the first time our grave concerns regarding the enormous financial consequences of the FDA's proposal for renaming all biological drugs.

The Agency has issued suffixes as a part of the non-proprietary name of all biosimilars approved to date, and recently to originator biologics that are approved for the first time. We also note that the Agency has not yet retroactively issued suffixes to any reference product for which there is a corresponding biosimilar. This inequity has created challenges in the naming protocols used within the US healthcare system.

There is no mention in the Biologics Price Competition and Innovation Act of 2009 of a naming convention for biologics, biosimilars, or interchangeable biologics. As such, there is no statutory barrier were the Agency to revert to the naming conventions that had been used prior to the advent of biosimilars.

In his presentation given at the Brookings Institution on July 18, 2018, Commissioner Scott Gottlieb stated that the Agency plans to retain the new biologics naming convention, believing that it has a greater potential for good in pharmacovigilance as measured against the likelihood for confusion and harm. While we continue to disagree, we respect this decision and as such believe that we need to move forward.

The NCPDP has two important requests:

1. **Agency needs to work with NCPDP:** The Agency needs to work closely with NCPDP as we revise the US systems by which biologics are distributed, dispensed and recorded. It is inappropriate and potentially dangerous if the Agency does not acknowledge the impact of the new biologics naming convention. Decisions being made now will have far-reaching consequences. NCPDP will be seeking a meeting with the Agency in the near future to further discuss this issue and identify appropriate solutions.

2. **Assess impact of the new biologics naming convention when pharmacovigilance data becomes available:** It is indisputable that the new biologics naming convention was developed in response to safety concerns that are, to date, hypothetical. NCPDP requests that, when adequate pharmacovigilance data is available, the Agency review whether or not pharmacovigilance has been improved, has been negatively impacted, or has had no impact in the tracking of adverse events for biosimilars and their corresponding reference products.

Uptake of biosimilars has been slow to date among the first tranche of biosimilars to be approved. However, we are aware that Zarxio® (figrastim-sndz) has been adopted widely with over two million patient days of exposure as of June 30, 2018 (communication from Sandoz). The Generics Bulletin of 31 August 2018 reports that "there have been 65 case reports since Zarxio®'s US launch, of which 62 (or 95%) included the biosimilar's brand name." The sponsor has clarified the remaining 3 reports contained the manufacturer's name, and none contained the "sndz" suffix. At the same time, there was no increase in adverse events reported to Agency's Adverse Events Reporting System Public Dashboard with the corresponding reference product (Neupogen® (filgrastim))[1], as there were 718 reports in 2016 and 691 reports one year later, in 2017.

NCPDP appreciates that this is the very first data set available from US sources with a biosimilar and that the available data set may be too small to justify a reversal of the newly adopted biologics naming convention. Additional Zarxio® safety data would be helpful, as well as data related to other biosimilars if and when such data becomes available. It is inevitable that such data will become available with time.

We urge that the Agency carefully review such pharmacovigilance data. If the data reveals that pharmacovigilance has been negatively impacted, the Agency should place the interests of patients first and reverse the decision to add suffixes to the non-proprietary name of biologics. As stated above, there is no statutory barrier were the Agency to drop use of suffixes in the naming of biological drugs.

NCPDP and its members look forward to working with the FDA to establish practical ways to ensure the safety and proper identification of biologics by use of standardized, unambiguous electronic medication information transfer.

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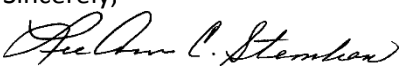
Sincerely,



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[1] https://fis.fda.gov/sense/app/777e9f4d-0cf8-448e-8068-f564c31baa25/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis; accessed May 16, 2018