October 27, 2015

Food and Drug Administration
Division of Dockets Management (HFA–305)
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852
http://www.regulations.gov

RE: Docket No. FDA–2013–D–1543 - Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability[1]
Docket No. FDA– 2015–N–0648 - Designation of Official Names and Proper Names for Certain Biological Products; Proposed Rule[2]

Dear Sir/Madam:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,500 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.

NCPDP provides the following comments in response to the notice on Nonproprietary Naming of Biological Products Draft Guidance for Industry Availability and to the Proposed Rule on Designation of Official Names and Proper Names for Certain Biological Products:

NCPDP General Comments:

1. **The employment of consistent standards and data structures accepted as valid by all parties in the pharmaceutical supply chain is critically important.** This is particularly true with any new standards FDA is promulgating and endorsing for broad use throughout the health care system[3]. Any changes must be explained to all stakeholders expected to use them. With revised naming for biologics, biosimilars and interchangeable biologics, user systems must be tested to ensure they can accommodate the proposed novel and currently non-standard formats.

2. **Nonproprietary naming conventions must be applied consistently to all products, including biologicals.** Sound scientific and regulatory reasoning underlies the current naming regimen, which has historically been supported by the FDA[4], as well as NCPDP. There has been no challenge to that reasoning and no evidence of a need for changes in addressing biosimilars and interchangeable biologics. Indeed, contrary evidence is presented by the successful approval and use of 22 biosimilar drugs in Europe *without* distinctive nonproprietary names. Likewise for the many currently approved and licensed biologics on the US market today that share nonproprietary names[5], but that are not being proposed for renaming in the initial Rule. The fact that some biologics are regulated under the Food, Drug and Cosmetics (FD&C) Act and some under the Public Health Service (PHS) Act does not create a distinction warranting a difference in the naming conventions applied to them, since the biologics regulated as drugs will become designated reference products for biosimilars in 2020. Yet apparently the FD&C Act biologic drugs are to remain with the current naming conventions and those licensed under the PHS Act are to change[6]. Additionally, the proposed biosimilar naming practice will create products that have *two* unique names – the manufacturer brand name and the unique nonproprietary name (itself a contradiction in terms) and no shared names, in sharp contrast to generic drugs, which share unique nonproprietary names and do not have unique proprietary names.

3. **Any revisions to the nonproprietary naming conventions must be reconciled with the statutory obligations of the United States Pharmacopeial Convention (USP) and the United States Adopted Names (USAN) council**. The proposed biosimilar protocol supersedes the historical role of both agencies, a role that FDA has historically respected and endorsed:

> "…established names (i.e., nonproprietary or generic name) do not undergo review by CDER. The United States Adopted Names Council (USAN) is responsible for selecting a United States Adopted Name (USAN) for drugs marketed in the U.S."[7]

4. **The development of US naming practices that are at odds with those employed internationally is not supportive of global harmonization.** The absence of coordination with the WHO's Biologics Qualifier initiatives[8] will result in the development of two systems that appear superficially similar but have fundamental differences with the inevitable result of confusion and patient safety risk. Further they will divorce the US from the global norms developed for patient safety worldwide.

5. A preferred alternative to the nonproprietary naming conventions should consist of **Tracking by NDC.** The biosimilar naming policy relies on the ability to track medications by NDC or other standard product identifier and would present a challenge to healthcare organizations that do not track products by NDC or other standard product identifier. Such organizations may apply a surrogate NDC to reflect an array of NDCs for related drug and biologic products. Although tracking by specific NDC remains a challenge for these healthcare organizations, it should reflect best practices rather than convenience or ease of implementation. Solutions should be developed that would ensure NDC-specific product tracking. Initially, this would involve the six biological products included in the FDA proposed rule.

There are two options available to these healthcare organizations that could be implemented until a more permanent solution is developed:

- The first is to apply the current Vaccine Adverse Event Reporting System (VAERS) model already in effect to the other biological and biosimilar products. This regulatory framework already exists for vaccines in all clinical settings and could be applied by FDA to ensure pharmacovigilance. In addition, consideration could be given to greatly simplifying the vaccine reporting requirements to meet FDA's current intent with the six proposed biologic products.
- The second option is to manually enter the NDC into the patient's electronic health record. Given that the current universe of biological and biosimilar products proposed by FDA is small, this could serve as an initial solution while a more permanent one is developed.

Hospital tracking of products by NDC will eventually be required under the Drug Quality and Security Act (P.L. 113-54). While full implementation of the law is still eight years away, compliance will eventually be required, underscoring the urgent need to begin developing a permanent solution to surrogate NDC application in hospitals.

NCPDP opposes the use of suffixes:

1. **A case for the inadequacy of the current system has not been made.** While the contention that existing practices for product identification are inadequate has been repeatedly advanced, no quantified evidence and little more than anecdotal support for that proposition has been offered. Further, insufficient or inaccurate recording of drug names will not be rectified by the deployment of a new system of identical base names with different insignificant suffixes. One could more credibly argue that, on the contrary, inadequate reporting will increase as a result of the increased complexity and the confusion inevitable in such a transition. If the argument is that the current ability to report INN plus brand name is insufficient to meet surveillance needs, it seems hard to argue that the same name plus a suffix will be the remedy.

2. **A clear definition of the problem to be solved and an identification of its true causes are essential preliminaries in any consideration of a new naming convention.** NCPDP believes the first step in searching for a solution to a problem, *e.g.* an inability to identify drugs involved in adverse events, is identifying the evidence that proves the problem is occurring to a meaningful extent. Such evidence, derived from FDA Adverse Event Reporting System (FAERS) or Periodic Safety Update Report (PSUR) reports for originator biologicals, can point to multiple potential causes, each of which must be evaluated, and they will define the metrics by which successful solutions are measured. With respect to biosimilar naming, those causes could be the design of the adverse event reporting system, the regularity and completeness of reporting practices, or underlying record-keeping, all of which present more plausible candidates for scrutiny than a drug's name. To put it another way, if people do not report completely or if systems do not require sufficient information, the use of a different name will have no effect.

3. **It is critical that, if any changes are to be considered, all stakeholders must be educated and engaged.** Dr. Woodcock addressed this specific issue at the September 17, 2015 Senate Health, Education, Labor and Pensions (HELP) Committee hearing and NCPDP agrees on the importance of communication and education prior to any new regulatory direction. NCPDP consequently requests that finalization of the Proposed Rule and Guidance be postponed until FDA can conduct a Part 15 hearing to hear the concerns of all impacted parties, and obtain their suggestions as to how to meet desired goals. NCPDP strongly believes there is a need for such a public meeting to permit all stakeholders to express their concerns about the potential downstream impact of the proposed regulations. If a case can be made for change, NCPDP efforts will be key in assisting a smooth implementation.

As we have noted previously[9], NCPDP and its members have been actively engaged on the issue of biosimilars for years. Our close attention to this area arises from our recognition that changes in drug identifiers can have profound and often insufficiently appreciated effects in the pharmaceutical workflow. Quality, economy and safety can be at risk when systems are unable to adapt to new procedures and the likelihood of miscommunication rises when all affected parties operate under different understandings. We therefore remain ready to work with you and other industry organizations to reach a consensus solution that achieves desired improvements while recognizing existing needs.

NCPDP looks forward to continuing our engagement with the FDA on this vitally important subject. Thank you for your consideration of our input.

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

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Sincerely,

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[1] FDA Federal Register Notice "Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability", 80 FR 52296, August 28, 201," Docket No. FDA-2013-D-1543 Available at: https://www.federalregister.gov/articles/2015/08/28/2015-21383/nonproprietary-naming-of-biological-products-draft-guidance-for-industry-availability (Accessed October 21, 2015)

[2] FDA Draft Guidance "Nonproprietary Naming of Biological Products", August 2015. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf (Accessed October 21, 2015).

[3] Proposed Rule on front page: See FDA Federal Register Notice, Proposed Rule "Designation of Official Names and Proper Names for Certain Biological Products," 80 FR 52224, August 28, 2015, Docket No. FDA-2015-N-0648. Available at: http://www.gpo.gov/fdsys/pkg/FR-2015-08-28/pdf/2015-21382.pdf (last accessed October 21, 2015).

> "FDA is proposing to take action with respect to these six products because of the need to **encourage routine usage of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices** for the biological products subject to this rulemaking, and to avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway."[emphasis added]

[4] Front page of FDA paper submitted to WHO, "U.S. FDA Considerations: Discussion by National Regulatory Authorities with World Health Organization (WHO) On Possible International Non-proprietary Name (INN) Policies for Biosimilars" (Sept. 2006). Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm375086.htm (Accessed October 21, 2015), noted as "Archived Content. The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived."

> "Support of INN's Original Purpose
>
> [ ] INNs should not be used to imply pharmacologic interchangeability of products with the same active ingredient(s) when no credible scientific data exist that demonstrate such. Likewise, INNs should not be used to differentiate products with the same active ingredient(s) when credible scientific data demonstrate that no pharmacologically relevant differences exist.

[5] McCamish, Gallaher, Orloff "Biosimilar by Name and Biosimilar by Nature", RPM Report, June 28, 2013. https://www.pharmamedtechbi.com/publications/rpm-report/9/7/biosimilar-by-name-and-biosimilar-by-nature (Accessed October 21, 2015)

[6] This topic was discussed on the FDA teleconference held on August 27th, 2015 and Dr. Woodcock said that how the 50% biologics drugs were to be handled had not yet been decided. Meanwhile, their nonproprietary names will apparently not change even though many of these nonproprietary names are shared between independently developed products from different sponsors, and in many cases the products are considerably more complex than the recently approved filgrastim biosimilar.

[7] How FDA Reviews Proposed Drug Names; available at http://www.fda.gov/downloads/Drugs/DrugSafety/MedicationErrors/ucm080867.pdf (Accessed October 21, 2015)

[8] WHO, "Biological Qualifier, An INN Proposal," Revised draft June 2015. Available at: http://www.who.int/medicines/services/inn/bq_innproposal201506.pdf.pdf?ua=1 (Accessed October 21, 2015).

[9] http://www.ncpdp.org/Resources/Hot-Topics