NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

VIA ELECTRONIC SUBMISSION: http://www.regulations.gov

May 7, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Submitted via

Re: Docket No. FDA-2013-D-1543 for "Nonproprietary Naming of Biological Products: Update"

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the draft guidance outlining the agency's updated policy on "Nonproprietary Naming of Biological Products." NACDS strongly supports policies that will cultivate confidence in biosimilars and promote use of more affordable biological alternatives. We are concerned that various changes to FDA's naming policies for biological products outlined in the updated guidance detract from achieving this goal. We appreciate FDA considering our views on this matter.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 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.

Position: FDA's updated naming policy for the nonproprietary naming of biological products will undermine prescriber and public confidence in biosimilar products. We have long expressed concerns to the agency with how the special naming scheme FDA has developed for biological products and applied (so far) to approved biosimilars is inconsistent with the naming conventions for brand and generic small molecule drugs. Whereas with small molecule drugs, the same individual nonproprietary name ("INN") is assigned to the reference drug and its generic counterpart, in contrast, new biological and biosimilar products will be given a "proper name" comprised of a "core name" that is shared by the innovator biological and any reference biosimilars, plus a random four-letter suffix that is unique to each product.

Over the years, physicians and patients have come to understand that a shared INN denotes that a generic product is at least comparable to the brand. However, deviating from this naming convention and applying unique proper names to biosimilars perpetuates the notion that biosimilars are not substantially comparable to the innovator biologic. Particularly for biosimilar products deemed interchangeable by FDA, this could lead to hesitancy by prescribers and patients to authorize substitution of more affordable interchangeable biological products.

It is critical that biosimilar products designated as interchangeable have the same nonproprietary name as the reference biological product. Although with small molecule drugs, shared names do not necessarily denote therapeutic equivalency, all therapeutically equivalent drugs do share the same name. Applying a new and different naming approach to biosimilar products deemed interchangeable is likely to lead to confusion among prescribers, dispensers, and patients that could lead to serious patient safety issues, increasing the risk that a dispenser may inappropriately interchange a product that was not deemed interchangeable by FDA. While the Purple Book is a publicly available resource for prescribers and dispensers to reference to determine whether a product is interchangeable, in the reality of busy practice settings, practitioners may be unlikely to reference this resource each time a biosimilar product is ordered or dispensed. Practitioners are in need of a clear and obvious way to confirm when a particular biosimilar is interchangeable with the reference product. A shared nonproprietary name effectively serves this purpose.

The updated naming policy creates a disparate system for already approved biological products and transition biological products. Applying the updated naming scheme to only newly approved innovator biological and biosimilar products going forward—while maintaining the current nonproprietary names of already approved biological products and transition biological products that do not currently include an FDA-designated suffix—exacerbates concerns that FDA's naming policy will undermine prescriber and public confidence in biosimilar products. A disparate system wherein some approved biological products have a core name without a suffix while others have a core name with an affixed four-letter suffix will make the previously approved biologics stand out from other biologics, perpetuating the notion that somehow the special naming scheme is warranted for certain products for safety reasons, but not others.

In addition, data systems across the healthcare industry would need to be modified to accommodate dual naming standards wherein only some products with shared core names are given a suffix while others are not. Not only does this complicate the process of maintaining clinically relevant drug relationships in data systems and applications, the associated implementation costs have been estimated by some to be in the billions.

The special naming scheme is not serving its intended purpose of improving pharmacovigilance systems. The special naming scheme that FDA has established for biological products is purportedly to improve pharmacovigilance practices by identifying the specific product dispensed to patients. However, data in the FDA Adverse Events Reporting System (FAERS) shows that the suffix is very rarely reported for products where this new naming scheme has been applied. As an example, data in the FAERS system through December 31, 2018 indicates that only 2 of the 3,380 adverse events attributed to "generic" adalimumab were reported with a product suffix.[1] Similarly, only 312 of the 4,068 adverse events attributed to "generic" filgrastim or a biosimilar product were reported with a product name.[2] This data demonstrates that attaching a special suffix to the core names of biological products does not serve the original, intended purpose and that unique nonproprietary names do not improve pharmacovigilance.

To improve existing pharmacovigilance practices, we urge FDA to put more resources into encouraging broader use of the NDC number in pharmacovigilance reporting. In the community pharmacy setting, pharmacy dispensing records include products' NDC number. This information can be accessed by healthcare practitioners for pharmacovigilance purposes to identify a particular manufacturer's product dispensed to a particular patient when there is an adverse event or other patient safety issue. While we recognize that not all healthcare settings retain this information, it is in the best interest of patients for FDA to work with stakeholders to identify and address existing deficiencies in recordkeeping practices to improve pharmacovigilance systems. Improving recordkeeping practices to include the NDC number will serve to improve pharmacovigilance practices for all types of dispensed medications, not just biological products.

Distinguishable nonproprietary names are unlikely to be used by prescribing clinicians in the manner that FDA hopes. In the updated guidance, FDA suggests that distinguishable nonproprietary names will "encourage routine use of FDA-designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices" to more broadly "facilitate accurate identification of these biological products by health care practitioners and patients." This concept for how the suffix should be used is inconsistent with real-life practice where

[1] Data drawn on April 12, 2019 from the FAERS system for ADALIMUMAB (g) and ADALIMUMAB-ADBM(g) identifies the following: For case count by product name, there were 3,380 adalimumab products reported as "generic" and 1 product reported as Imraldi (P); For case count by "generic" name, there were 401,082 adalimumab products reported by the "generic" name Adalimumab (G) and 2 products reported by the "generic" name Adalimumab-Adbm (G).

[2] Data drawn on April 12, 2019 from the FAERS system for FILGRASTIM (g) and FILGRASTIM-SNDZ(g) identifies the following: For case count by product name, there were 3,672 filgrastim products reported as "generic", 311 products reported as Xarxio (P), and 85 products reported as Granulokine (P); For case count by "generic" name, there were 11,495 products reported by the "generic" name Filgrastim (G) and 312 products reported by the "generic" name Filgrastim-Sndz (G).

prescribers commonly issue prescriptions using a product's brand/marketed name and provide directions to the dispensing pharmacist authorizing substitution (or not) on the prescription. It is unrealistic to expect that prescribers will deviate from common prescribing processes and use medications' proper names (instead of the trade name) when prescribing a biological product, especially given that the suffixes are nonsensical, devoid of meaning, and highly unlikely to be recalled by healthcare providers at the point of issuing a prescription.[3]

Applying a four-letter suffix to the core name of vaccines would be problematic. As FDA noted in the March 8 Federal Register Notice announcing the availability of the updated guidance, already existing systems associated with the administration of vaccines are robust and adequately ensure safe dispensing practices and optimal pharmacovigilance without requiring distinguishable proper names. Applying unique nonproprietary names for vaccines would only complicate the reporting of administered vaccines to state health registries and other systems.

Additionally, many vaccines have extremely long and complex nonproprietary names – particularly with combination vaccine products. The addition of a suffix to existing nonproprietary vaccine names would complicate the identification of such vaccine products in health information technology systems, as modified nonproprietary names could exceed the character limits of existing information systems.

FDA's naming approach for biologicals is inconsistent with the naming practices of other countries. In Canada, across Europe, and in other countries throughout the world, regulatory agencies do not apply a special suffix to biological products. In fact, Health Canada recently rejected this naming scheme and moved to a naming system devoid of the confusing suffix-based system.[4] FDA's continued application of suffixes to the nonproprietary name of biological products puts the United States out of step with the rest of the world.

Should FDA not accept our recommendation to eliminate use of the suffix, we alternatively recommend the following changes to FDA's naming policies outlined in the updated draft guidance on nonproprietary naming of biological products:

- Biosimilar products deemed interchangeable with the reference innovator biological should share the same proper name (i.e. be assigned the same core name and the same four-letter suffix.)

[3] Given that FDA's broader goal is for prescribers to be able to identify the specific biological product that their patient receives, a more effective and less problematic mechanism for identifying this information is a product's NDC number.
[4] https://www.bigmoleculewatch.com/2019/02/20/health-canada-drops-suffix-in-biologic-and-biosimilar-naming-convention/

- Previously approved biological products and transition biological products that do not currently include an FDA-designated suffix should be subject to the new naming policies and be assigned a proper name comprised of a core name plus a four-letter suffix.
- Vaccines should not be subject to the new naming policies that FDA applies to other biological products.

In conclusion. Although many biological products are currently administered in clinical settings, this naming policy will have a notable impact in the community pharmacy setting as the number of biological products that can be dispensed at retail grows. Moreover, with the recent push to promote the development of biosimilar insulin, the implications of FDA's naming policy will be far reaching. It is critical that FDA's naming policies foster confidence in biosimilar medications and promote a robust biosimilar market. We urge FDA to make the appropriation modifications to its naming policy for nonproprietary naming of biological products to ensure that naming practices do not undermine this goal.

NACDS thanks FDA for the opportunity to communicate our perspectives on the agency's updated policy on nonproprietary naming of biological products. Given the potential patient safety implications of FDA's naming policy, we appreciate FDA's consideration of our comments.

Sincerely,

Michelle Cope
Director, Federal and State Public Policy, NACDS