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Via Electronic Submission
http://www.regulations.gov

October 27, 2015

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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

CVS Health appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) in response to the draft guidance titled "Nonproprietary Naming of Biological Products; Draft Guidance for Industry."

CVS Health is the leading provider of prescriptions in the nation, with over one billion prescriptions filled or managed annually. There are over 26,000 pharmacists and over 7,900 CVS/pharmacy retail stores within our company, and we are also a leading specialty and mail pharmacy services provider. We operate over 1,000 MinuteClinic locations in 28 states and the District of Columbia that employ over 2,500 combined nurse practitioners and physicians' assistants, providing convenient access to routine health care services.

In the draft guidance, the FDA indicates its current thinking is for each product to have nonproprietary name that includes an FDA-designated suffix. The Agency indicates that it perceives a need to identify biological products to improve pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable. The FDA indicates that it intends to designate a nonproprietary name that includes a suffix composed of four lowercase letters for each product, including the originator product.

A major goal of the Biologics Price Competition and Innovation Act (BPCIA), passed as part of the Affordable Care Act (ACA), was to create competition in the marketplace for biologics, thereby expanding access to and increasing the affordability of biologic medications. The draft guidance on the nonproprietary naming of biological products will undermine these goals of increasing biosimilar patient access and market competition. A report recently released on the economic viability of the U.S. biosimilars industry suggests that regulatory barriers to uptake, including a possible FDA decision to require different international nonproprietary names (INNs), could impede the growth of the biosimilars marketplace if the regulatory framework is not determined to be conducive to manufacturers'

bringing products to market.[1] With several biosimilars currently awaiting FDA approval, this draft guidance could have deleterious effects on the development of affordable and accessible biosimilar products and a robust and vibrant market for biosimilar products.

CVS Health is aware that some groups have questioned the ability to track biosimilar products in the event of an adverse event and have requested that the FDA assign distinguishable names to reference biologics and biosimilars. CVS Health, through our retail and specialty pharmacies, has used the mechanisms currently in place successfully to appropriately monitor and manage recalls for generic small-molecule medications for years, as have all other pharmacies, and we know that those mechanisms are sufficient. We are concerned that any unnecessary changes may interfere with current pharmacy safety alert systems used today. In addition, because adverse events and product recalls for small-molecule and biologic drugs already are successfully identified using the national drug code (NDC code) and lot number, there is no compelling evidence that biosimilars should be handled differently. Shared INNs currently used (e.g., erythropoietins, somatropin, interferon) have not resulted in any known issues.

It is important that FDA considers the technical implications of unique names. The National Council for Prescription Drug Programs (NCPDP) is on record stating that existing software would need to be updated in order to group Neupogen® (filgrastim) and Zarxio® (filgrastim-sndz) together.[2] Today, this happens automatically for drugs that have the same active ingredient and INN. Creating unique names for biologics could result in biosimilars with the same active ingredient, but different INNs, being in different categories than the reference product in provider databases. According to NCPDP, unique INNs would require some type of mapping to link products that would traditionally share an INN. Each database warehouse would make these decisions independent of other database warehouses, resulting in greater complexity and the likelihood of confusion. NCPDP also has examples of where prefixes added to INNs (*e.g.*, tbo-filgrastim) were dropped in some dispensing systems, which resulted in confusion. The same problems could arise with suffixes. This confusion among pharmacists, payers, and prescription benefit managers (PBMs) could create significant disruption, adversely affecting patient access to these important medications.

The legislative intent of the biosimilar approval pathway included in ACA was to support the development of less expensive but equally effective alternatives to biologic drugs. Requiring different INNs would create an unnecessary barrier to the benefits of FDA-determined interchangeability. Patients, prescribers and dispensers of these drugs need to be able to easily identify which drugs bear a relation to one another in order to maximize the potential savings from the biosimilar approval pathway. It will be difficult for pharmacists and physicians to remember and differentiate nonproprietary names of biosimilar(s) and originator brand for a given product, when each nonproprietary name is composed of the same 'core name' plus a random/meaningless four-letter suffix. This naming convention could increase the rate of prescribing and dispensing errors compared to use of a naming convention in which the name is

[1] Brill, Alex. The Economic Viability of a U.S. Biosimilars Market. February 2105. http://www.matrixglobaladvisors.com/storage/mga_biosimilars_2015_web.pdf.

[2] Gingery, Derrick. "Biosimilar Naming Is Challenge for Provider Databases." *The Pink Sheet.* March 16, 2015.

composed of the same 'core name' plus a meaningful four-letter suffix. CVS Health strongly reiterates that any departure from the currently accepted INN system could disrupt current processes to dispense and track these medicines, risking provider confusion and patient safety. The adoption of a unique non-proprietary name could jeopardize patient safety, which is counter to the mission of the FDA. Therefore, CVS Health believes all guidance on this matter should require that reference biologics and biosimilars have the same INN.

For the above reasons, CVS Health strongly opposes the proposed use of a suffix to name biosimilars and believes that the agency should instead remain consistent with its longstanding practice to keep shared naming for equivalent products from different manufacturers.

Thank you for your careful consideration of this important matter. We welcome the opportunity to work with you to ensure that the new biosimilar market in the United States gives patients access to safe, effective and more affordable alternatives to brand-name biologics. If you have any questions, please feel free to contact Marissa Schlaifer, Head of Policy, at (202) 772-3538 or marissa.schlaifer@cvshealth.com.

Sincerely,

Melissa Schulman
Senior Vice President, Government Affairs