



APhA

2215 Constitution Avenue, NW • Washington, DC 20037-2985

May 7, 2019

Re: Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry; Availability (Docket No. FDA-2013-D-1543)

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide comments in response to the Food and Drug Administration (FDA) Guidance for Industry, “Nonproprietary Naming of Biological Products: Update” (hereinafter, “Draft Guidance”). APhA, founded in 1852 as the American Pharmaceutical Association represents 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

While APhA appreciates FDA intent to clarify the agency’s thinking on nonproprietary names of biological products, we offer the following responses regarding the Draft Guidance.

I. Unintended Consequences

APhA is concerned the Draft Guidance does not provide clear justification to support this shift in policy and potential unintended consequences related to biological products broadly. For example, the Draft Guidance states “the approach is intended to minimize confusion for healthcare providers and patients, given the nonproprietary names of drugs seldom change post-approval.” By not addressing healthcare providers’ and patients’ confusion stemming from variable naming practices for non-transition biological products¹, it is implied that FDA considered only the impact retrospective naming changes have on specific product uptake rather than perceptions variable naming confers on all biological products.

As more biological products are approved, a growing proportion will have a suffix. Consequently, efforts to reduce confusion for a relatively small subset of products could have far-reaching implications regarding future perceptions of biological products. Therefore, APhA encourages FDA to address and potentially expand its evaluation of potential unintended consequences before finalizing the Draft Guidance.

II. Product Identification

¹ According to the glossary provided in the Draft Guidance, a “transition biological product” means Transition Biological Product means a biological product that is the subject of an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as of March 23, 2020, that will be deemed to be a biologics license application (BLA) under section 351 of the PHS Act on March 23, 2020 (see section 7002(e)(4) of the BPCI Act).



APhA

2215 Constitution Avenue, NW • Washington, DC 20037-2985

APhA is concerned alternative naming protocols for biologic products could confuse pharmacists', other healthcare providers' and patients' understanding of the product they are using. For example, labeling practices that previously relied on the core name may need to be reconsidered as, for some products, the core name will also be the nonproprietary name. Consequently, education and notice will need to be provided to patients and health care practitioners regarding variable product names to help understand product labeling involving transition biological products and non-transition biological products. APhA suggests FDA to work with health care practitioners and patients among other stakeholder to learn whether such naming variability within products' labeling will add confusion and to then consider and test potential solutions.

III. Pharmacovigilance

As FDA knows, attention must be paid to products with a suffix ensure accurate prescribing, dispensing and adverse event reporting. APhA is aware of reports that adverse event data for biological products more commonly use the product's brand name opposed to the nonproprietary name. APhA encourages FDA to consider and contrast pharmacovigilance efforts with currently approved medications, including transition biological products and more recently approved biologics to determine whether adverse event reporting is impacted by the existence of a suffix. Such information may also help inform alternative or complementary pharmacovigilance opportunities.

IV. Care Implications

As FDA is likely aware, the medication a patient receives is partially dependent on payer coverage. Pharmacy systems and related technology standards help ease pharmacists' work flow and receive information from plans related to coverage of a patient's prescription. When a patient's prescription is changed for reasons related to coverage, pharmacists spend time counseling the patient and communicating with the plan and prescribers.² APhA encourages FDA to also consider implications on pharmacists' work flow and additional time that may be needed to counsel patients as it evaluates options for naming conventions.

V. Vaccine Suffixes

Consistent with APhA's view that a suffix is not needed for biological products, APhA recommends FDA refrain from modifying vaccine naming conventions. APhA believes adding a suffix to vaccine names will be confusing and given the importance of vaccines for public health, a variable naming convention could support misinformation efforts that question vaccine quality and safety.

² See American Pharmacists Association, (2017) "Proceedings: Assessing Pharmacists' Awareness of the Follow-On Insulin Market, Nonmedical Product Switching and Its Impact on Patient Care", available at: https://www.pharmacist.com/sites/default/files/files/17005_Cover_Hi.pdf



APhA

2215 Constitution Avenue, NW • Washington, DC 20037-2985

APhA supports FDA's efforts to improve safety, protect public health and advance the development of biological products. Should you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Mitchel C. Rothholz, RPh, MBA
Chief Strategy Officer