



VIA Electronic Submission to <http://www.regulations.gov>

May 25, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: [Docket No. FDA-2011-D-0618] Draft Guidances Relating to the Development of Biosimilar Products; Public Hearing; Request for Comments; Correction

Dear Sir or Madam:

The American Pharmacists Association (APhA), the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) thank you for the opportunity to share the perspectives of community pharmacists and pharmacies as the Food and Drug Administration (FDA) finalizes the draft guidances related to the development of biosimilar products.

APhA founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 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, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their \$900 billion in annual sales.

NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together, they represent a \$93 billion health-care marketplace, employ over 300,000 employees including 62,400 pharmacists, and dispense over 40% of all retail prescriptions.

Together, our organizations support the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which offers an opportunity to increase patient access to cost-effective, life-saving or life-altering treatments by creating an abbreviated pathway for FDA-approved biosimilars determined to be highly similar or interchangeable with their reference products.

Our organizations share many of the same concerns and interests regarding what will be included in the final guidance documents and we respectfully submit our comments on behalf of the community pharmacy profession.

Pharmacists will be greatly impacted by the decisions made on how the biosimilar approval pathway is implemented. Pharmacists are the most accessible healthcare professionals and recommending generic alternatives is a standard pharmacy practice. Allowing pharmacists to perform fully within their scope of practice by permitting automatic substitution of cost-effective biologic and specialty medications increases availability, thereby greatly benefitting the entire health care system and the patients it serves. Overall, generic medications increase public access to crucial medications and save billions of dollars. According to a recent IMS Institute for Healthcare Informatics report, generic use generated more than \$157 billion in savings in 2010 alone.¹ We expect to see cost savings with biosimilars as well and need to ensure smooth implementation for dispensing of biosimilars and interchangeable biosimilars.

Naming Considerations

To avoid a naming convention that may create confusion, we recommend that biosimilar products maintain the same name as their reference biologic counterparts and not use suffixes. We are concerned that mandating the use of unique individual nonproprietary names (INNs) could create the very public health issues that the FDA wishes to avoid: therapeutic duplication and general confusion relative to the appropriate use, safety and efficacy of biologic products.

Unique INNs for common active ingredients may generally increase confusion, leading to increased safety concerns and possibly medication errors. Physicians are already pressed for time, and therefore it is imperative that there are no additional and unnecessary obstacles that hinder them from timely decision-making, especially in cases of urgent care. The use of different INNs would increase the burden of being able to distinguish which products are biosimilar and interchangeable with which reference drug and may pose difficulties in recognizing the best alternative drug for therapeutic use in a timely manner. Such confusion may lead to medication errors such as therapeutic duplication. Furthermore, unique INNs would be contrary to the World Health Organization (WHO) naming system that is accepted globally, causing confusion within the global marketplace.

We acknowledge that the ability to uniquely identify which biological product a patient is taking is important, especially in cases of adverse events and quality issues. However, the use of INNs is not a warranted solution and may interfere with current pharmacy safety alert systems and complicate the collection of global safety information. Using examples of successful biopharmaceuticals marketed under the same INN, such as human growth hormone and insulin, the FDA can apply the same concept for naming the biosimilar products. The same INN will not necessarily denote interchangeability, but rather be used to categorize a similar therapeutic drug. For the purposes of identifying a product, a unique identifier, such as an NDC code that pharmacies already use to track products, can be used to track the specific drug that a patient is prescribed. We recognize that non-pharmacy dispensing settings may not currently track by NDC number.

¹ IMS Institute for Healthcare Informatics. The Use of Medicines in the United States: Review of 2011. April 2012. (<http://www.imshealth.com/portal/site/ims/menuitem.200f6c7c03de2b548b1152113208c22a/?vgnextoid=82ec3fc68b876310VgnVCM10000076192ca2RCRD>).

We recommend FDA and stakeholders consider solutions to retool such systems to allow for tracking by NDC number. In addition, given the different systems and process standards used in inpatient and outpatient settings, best efforts must be made to ensure that solutions work for all practice settings.

In 2006, the FDA concluded to its global regulatory peers that “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.”² Our organizations continue to support and find relevance in this stance as it applies today to biosimilars.

Automatic Substitution of Biosimilar Interchangeable Products by Pharmacists

According to section 351(i)(3) of the Public Health Service (PHS) Act, interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider. We trust the FDA’s knowledge and its 15+ years of experience of comparing biologics and determining interchangeability. When a biosimilar product is approved by the FDA as interchangeable to its reference product, we have confidence that the FDA made that decision after thorough consideration. Therefore, we believe that if the FDA deems interchangeability between products, pharmacists should be able to automatically substitute biosimilar interchangeable products as it is currently regulated under the PHS Act.

Further FDA Guidances Necessary to Define and Determine Interchangeability

We request that the FDA provide further guidance regarding whether biosimilar medicines will be determined to be interchangeable with their reference products, how pharmacists can assess appropriateness of substitution for individual patients, labeling provisions for manufacturers, and prescribing standards for physicians. In addition, we support the development of an FDA compiled interchangeability reference list, something similar to the current Orange Book for generics, to assist health care providers in managing these prescription orders.

We support the FDA as they continue to consider the type of information sufficient to enable them to determine that a biological product is interchangeable with the reference product, since careful considerations must be made to ensure that the patients’ safety and efficacy are not compromised. We encourage FDA to ensure that such consideration and decisions for standards for interchangeability not delay the industry from providing important cost-effective biosimilars to patients.

² WHO Informal Consultation on International Nonproprietary Names (INN) Policy for Biosimillar Products. Presentation from FDA. September 2006. http://www.who.int/medicines/services/inn/BiosimilarsINN_Report.pdf.

Education and Outreach

Our organizations recognize the need for education and training of health care providers on biosimilars. Education and outreach will need to focus on a number of issues, including, but not limited to: awareness, identification of biosimilars and interchangeables, terminology, processes and logistics to prescribe and dispense biologics and importantly those that are determined to be interchangeable, differences from current generic process, and necessary resources.

There will be a learning curve before, during, and after products complete the biosimilar pathway to market. Again, we will need education and awareness campaigns on how to handle these products and the logistics for prescribing and dispensing. Our organizations are willing to work with FDA and other stakeholders to help develop and provide education to pharmacists through vehicles such as: continuing education programs, print and online communication tools, and other outreach opportunities.

Conclusion

Again, we support FDA's ongoing efforts to ensure a successful implementation of the biosimilar pathway. Thank you for the opportunity to provide comments on the draft industry guidance documents, which may improve health care access to medications for life-saving and debilitating diseases. We appreciate your consideration of the information above and look forward to working with the FDA and other stakeholders on this important issue.

Sincerely,

American Pharmacists Association
National Association of Chain Drug Stores
National Community Pharmacists Association

For additional information, please contact:

Marcie Bough, PharmD
Senior Director, Government Affairs
American Pharmacists Association

Kevin N. Nicholson, R.Ph., J.D.
Vice President, Pharmacy Advisor
Government Affairs and Public Policy
National Association of Chain Drug Stores

Ronna Hauser, Pharm.D.
Vice President, Policy and Regulatory Affairs
National Community Pharmacists Association