Academy of Managed Care Pharmacy®

October 19, 2016

Food and Drug Administration
Division of Dockets Management (HFA-305)
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Biosimilar User Fee Act: Public Meeting; Request for Comments
[FDA-2015-N-3326-0012]

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments on the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years 2018 through 2022 as published in the *Federal Register* on September 13, 2016. These written comments are provided in addition to the oral comments AMCP will present at the public meeting on October 20, 2016.

AMCP fully supports the implementation of a robust biosimilars pathway to ensure that Americans receive access to safe, effective, and affordable biologics and biosimilars. AMCP supports efforts, including BsUFA, to establish expeditious review processes to ensure access to these important therapies for the American public. AMCP's comments focus on the following areas:

- Need for drafting, revising, and/or finalizing several guidance documents as described in Section II of the commitment letter. Specifically, guidance documents that address naming, labeling, and interchangeability. Not only should these guidance documents be published as quickly as possible, but the FDA must also ensure they are harmonious with one another to provide the additional consistency and clarity necessary to truly operationalize the biosimilars pathway;

- Need for FDA to encourage use of active post-marketing surveillance for biologics and biosimilars and publish guidance in this area; and

100 North Pitt Street | Suite 400
Alexandria, VA 22314
800 827 2627 | 703 683 8416
Fax 703 683 8417
www.amcp.org

- Support efforts for training and the development of educational resources as described in Section III of the commitment letter, including the adoption and dissemination of existing educational resources, such as AMCP's Biosimilars Resource Center (BRC)[1], to provide neutral, unbiased educational resources to pharmacists, physicians, nurses, and other health care providers.

AMCP is a national professional association of pharmacists, physicians, nurses, and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's nearly 8,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy benefits.

Comments on Section II: Advancing Development of Biosimilar Biological Products through Further Clarification of the 351(k) Regulatory Pathway

AMCP appreciates FDA's clarification on deadlines to release several draft guidance documents (*Interchangeability; Statistical Considerations for Analysis of Analytic Data to Support "Highly Similar; and Post-Approval Marketing Changes*) and several revised drafts and/or final guidance documents (*Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product*, *Nonproprietary Naming of Biological Products*, and *Labeling for Biosimilar Biological Products)*. To ensure that stakeholders have as much certainty on the pathway as possible, AMCP supports publication of these documents as expeditiously as possible and before the proposed deadlines. In addition, FDA must ensure that the guidance documents are harmonious with one another.

Clear Guidance on Interchangeability is Necessary as Quickly as Possible and Must Ensure that Access to These Agents is Not Hindered by Unnecessary Dispensing and Recordkeeping Requirements

AMCP is particularly concerned about the release of initial draft guidance related to interchangeability. As more biosimilars are approved and marketed, patients, health care systems, providers, payers, and federal and state policy makers must be informed about policies for interchangeability. Health care providers, in particular pharmacists who often make recommendations to patients related to the use of medications, including biologics, require clear guidance on interchangeability to ensure that patients receive the appropriate medication. This guidance must contain information that must be recorded in FDA's *Purple Book* which will serve as the primary resource for health care provider information about biologic and biosimilar products. Health care decision makers, including managed care pharmacists, physicians, and nurses who make formulary decisions for populations must also have clear guidance about interchangeable biological products. Electronic health record systems and databases used for purposes of payment, prescribing, dispensing, distribution and other health care

[1] The Biosimilars Resource Center (BRC) provides educational resources and information on biosimilars to health care providers and other stakeholders in a policy-neutral and non-promotional manner. Biosimilars have the potential to significantly decrease health care costs in the United States and improve access to treatment for patients. The need for education of health care providers on how to prescribe and dispense cost effective biosimilars is critical to driving adoption and maximizing their use in a safe and effective manner for patients. The BRC provides access to educational tools and training materials for biosimilars, including one-pagers, web-based educational seminars, continuing education and journal articles. The BRC was launched in 2016 by the Academy of Managed Care Pharmacy in partnership with the American Association of Colleges of Pharmacy, America's Health Insurance Plans, the American Pharmacists Association, the American Society of Consultant Pharmacists, the Hematology/Oncology Pharmacists Association, the National Alliance of State Pharmacy Associations, and the National Community Pharmacists Association.For more information on the BRC, please visit https://www.biosimilarsresourcecenter.org/.

functions must have clear guidance to be properly programmed to ensure that information is conveyed and shared safely, accurately, and efficiently.

To this end, AMCP supports FDA interchangeability guidance that provides clear rules for the designation of a biosimilar product as interchangeable with a reference product, similar to the current "AB" ratings used for small-molecule chemical drugs.[2] AMCP believes that the FDA should implement a two-step process with the first step determining the biosimilarity of an applicant product and the second step determining the interchangeability of the biosimilar with the reference product. A determination of interchangeability should not be a requirement as a condition for approval of a biosimilar product and interchangeable products should not be granted additional exclusivity. AMCP believes that the states should follow FDA's determination of interchangeability with regards to granting substitution authority to pharmacists. Therefore, AMCP opposes unnecessary requirements for prescriber notification of the product dispensed when the FDA has designated the products as interchangeable.[3]

AMCP is particularly concerned that interchangeability guidance may conflict with or create confusion related to existing state laws related to biosimilars. Currently, 25 states[4] have laws in place that define interchangeability even before FDA has finalized its pathway or fully defined interchangeability. For this reason, AMCP continues to oppose state legislation that seeks to define interchangeable biologic products or requires additional steps for pharmacists to take when dispensing these products before the draft guidance. Given the number of biosimilars currently approved and marketed and steps taken by states prior to FDA finalizing the pathway, AMCP encourages FDA to release its draft interchangeability guidance before the proposed December 2017 deadline.

FDA Should Issue Final Guidance on Nonproprietary Naming and Labeling without Further Comment Period to Provide Clarity and Consistency to Stakeholders

AMCP urges FDA to finalize guidance documents related to naming and labeling in a timely manner and not to re-issue draft guidance with an additional comment period. AMCP had previously suggested that FDA re-release naming guidance with a new comment period, but in light of recent actions related to biosimilar approvals with naming conventions, FDA should finalize its intent as soon as possible to provide needed clarity and consistency in the biosimilars pathway.

AMCP reiterates its concerns with the draft naming guidance and FDA's proposal to adopt a four letter randomized hyphenated suffix affixed to the nonproprietary name. AMCP has been seeking a decision from the FDA regarding biosimilar naming for several years and is disappointed with FDA's proposal. AMCP continues to support the use of the international nonproprietary name for both biologics and biosimilars with no prefix or suffix. Rather than using a prefix or a suffix, AMCP supports the use of the National Drug Code (NDC) on all claims for medications, including biologics and biosimilars. The use of NDCs along with lot number and manufacturer name provides an existing mechanism to individually identify products. Prior to finalization of the naming guidance, AMCP urges FDA to carefully consider the ramifications of using a suffix and to provide

[2] A product receives an AB rating if the FDA has determined that it contains identical active ingredient(s), dosage form, and route(s) of administration and has the same strength as the brand-name product.
[3] Where We Stand: Biosimilar Drug Therapies. AMCP: July 2015. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20018. Accessed October 16, 2016.
[4] States with laws related to biosimilars and biologic products Arizona, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Missouri, New Jersey, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Virginia, and Washington, Puerto Rico. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20720. Accessed October 18, 2016.

results from cognition testing on pharmacists, physicians and other providers and patients demonstrating that the proposed naming framework adds value to the public safety, is easily understood and comprehended by the public, and does not result in increased confusion.

Regardless of FDA's final decision on biological naming, it should strive to ensure consistency in the naming process and avoid any additional confusion. To date, all reference biologic products are named without using a suffix, one biosimilar product is named using a non-randomized suffix (filgrastrim-sndz), and the remaining products are named with using a randomized suffix (infliximab-dyyb; etanercept-szzs; and, adalimumab-atto). Furthermore, one biologic product, tbo-filgrastim, uses a prefix. These disparities in naming and the resulting confusion and possible patient safety concerns that could result demonstrate the need for final guidance in this area in an expedited manner.

In regard to labeling, FDA should consider comments received by stakeholders in response to the August 2016 deadline on its draft guidance document and issue final guidance as expeditiously as possible. AMCP recommended that the biosimilarity statement be removed because it is unprecedented in medication approvals and may lead health care providers and patients to unnecessary conclusions that biosimilars are not safe and effective in comparison to the reference product. AMCP also supports that FDA finalize naming guidance prior to finalizing labeling to ensure consistency and harmony in the use of naming conventions on the label.

FDA Should Encourage the Use of Active Post-Marketing Surveillance in Determining the Real World Effectiveness of Biologics and Biosimilars

As FDA finalizes policies on the biosimilars pathway, it should consider the use of active post-marketing surveillance to determine the safety and efficacy of biologics and biosimilars in patients outside of clinical trials. FDA has indicated support for these efforts but should provide additional guidance on use of this information.

Comments on Section III: Enhancing Capacity for Biosimilar Regulations and Guidance Development, Reviewer Training, and Timely Communication

AMCP's Online BRC Can Help FDA Promote Biosimilar Education

AMCP is pleased that FDA has committed to providing additional resources and staffing to educate patients and other stakeholders on the issue of biosimilars. AMCP shares this commitment, and in June 2016, launched the Biosimilars Resource Center (BRC) which is available at www.biosimilarsresourcecenter.org. The BRC provides an unbiased, policy-neutral repository of educational resources and information on biosimilars for pharmacists, physicians, nurses and others. Other pharmacy and payer organizations that have joined AMCP as partners in its efforts are the American Association of Colleges of Pharmacy (AACP), America's Health Insurance Plans (AHIP), the American Pharmacists Association (APhA), the American Society of Consultant Pharmacists (ASCP), the Hematology/Oncology Pharmacists Association (HOPA), the National Alliance of State Pharmacy Associations (NASPA), and the National Community Pharmacists Association (NCPA).

The BRC website includes information from FDA's website, including continuing education for health care providers on FDALearn. In 2017, AMCP intends to enhance information and resources on the website and also expand biosimilars education offerings, including webinars and live seminars to health care providers. The BRC can help FDA disseminate educational resources and information. AMCP looks forward to partnering with FDA on providing education and resources on biosimilars.

Enhancement to the Purple Book Using BSUFA Funds is Necessary to Provide Clarity About Biologics and Biosimilars for Health Care Providers to Ensure Safe and Effective Use

AMCP supports FDA's efforts to hire additional staff to enhance the *Purple Book* to include comprehensive information about biologics, including the biologics license application (BLA) number, product name, proprietary name, date of licensure, interchangeable or biosimilar determination, and date of withdrawal or approval. As noted above, health care providers must rely on a single, comprehensive, neutral and reliable source of information for biologics and biosimilars. For many years, pharmacists and other health care providers have relied on the FDA's *Orange Book* for small molecule agents and therefore, it logically follows that the FDA should maintain a similar comprehensive resource for biologics and biosimilars.

Thank you for the opportunity to submit comments to the docket and to present comments at the live meeting. AMCP looks forward to continuing our work with FDA to ensure access to safe and effective biologic and biosimilar products, particularly in the area of education about biosimilars. If you have any questions, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer