



October 26, 2015

2015

President

David A. Williams, MD
Chief, Division of Hematology/Oncology
Children's Hospital Boston
300 Longwood Avenue, Karp 8
Boston, MA 02115
phone 617-919-2697
fax 617-730-0934
dawilliams@childrens.harvard.edu

President-Elect

Charles S. Abrams, MD
421 Curie Boulevard, #812
Philadelphia, PA 19104-6140
phone 215-573-3288
fax 215-573-7400
abrams@mail.med.upenn.edu

Vice President

Kenneth C. Anderson, MD
Dana-Farber Cancer Institute
450 Brookline Avenue, Room M557
Boston, MA 02115-5450
phone 617-632-2144
fax 617-632-2140
kenneth_anderson@dfci.harvard.edu

Secretary

Stephanie J. Lee, MD, MPH
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North, D5-290
PO Box 19024
Seattle, WA 98109
phone 206-667-5160
fax 206-667-1034
sjlee@fhrc.org

Treasurer

Susan B. Shurin, MD
222 Quince Street
Unit 2C
San Diego, CA 92103
phone 240-328-8542
sxs15@yahoo.com

Councillors

Joseph Connors, MD
Mary C. Dinauer, MD, PhD
Terry Gemsheimer, MD
Michelle M. Le Beau, PhD
Jonathan D. Licht, MD
Margaret A. Shipp, MD
Martin S. Tallman, MD
John Winkelmann, MD

Editors-in-Chief

Bob Lowenberg, MD, PhD, *Blood*
Jason Gotlib, MD, *The Hematologist*
Mikhael Sekeres, MD, *ASH Clinical News*

Executive Director

Martha L. Liggett, Esq.
mliggett@hematology.org

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

Re: Docket No. FDA-2013-D-1543-0001: Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability

Dear Sir or Madam,

The American Society of Hematology (ASH) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) in response to the Agency's Draft Guidance for Industry: Nonproprietary Naming of Biological Products as published in the Federal Register (FDA-2013-D-1543-0001) on August 28, 2015.

ASH represents more than 15,000 clinicians and scientists worldwide committed to the study and treatment of blood and blood-related diseases. These diseases encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma and non-malignant conditions such as hemophilia, sickle cell anemia, and venous thromboembolism. ASH members include clinicians who regularly render services to patients who require biological products as part of their treatment protocol. Thus, ASH is very interested in the FDA's guidance on the naming of biologics and its impact on patient safety, care and access to important therapies. ASH commends the FDA for its ongoing efforts in these areas, including seeking input from stakeholders.

ASH agrees with the FDA's decision to require biologics and biosimilars to have unique names that would include a suffix. Unique names will minimize inadvertent substitution of products not determined to be interchangeable by the FDA. They will also help facilitate proper and safe use of these treatments. ASH believes that distinguishable names will enable better tracking of prescriptions and any adverse events associated with these drugs thus facilitating a robust pharmacovigilance system that increases patient safety.

ASH strongly believes that treatment decisions should be made by physicians and their patients. Thus, ASH is concerned that the draft guidance states that biosimilars deemed to be "interchangeable" may be substituted with a reference product by a pharmacist, without consultation of the prescribing physician. ASH believes there should be no automatic substitution of biosimilars for biologics unless the prescribing physician explicitly approves it. Short of this, ASH encourages the FDA to develop a policy that requires notification to the prescribing physician and patient prior to any substitution being made. The use of distinguishable names would support these practices.

ASH also agrees that the suffixes for biosimilars should be distinctive. We recommend that the FDA consider the following when deciding how the suffixes should be developed: i) suffixes “devoid of meaning” (i.e. corename.xspk) are difficult to remember and can cause confusion in related communication; ii) naming conventions with “meaningful” suffixes that utilize a company’s name (i.e. corename.amgn) could also create confusion, for example, if a company has multiple versions of the therapy, if the company merges with another company, or if the company changes its name.

Finally, ASH believes that it is imperative for the FDA to have a strategic communication plan to ensure stakeholders’ understanding of the final naming convention. ASH recommends that the plan include educational sessions at national meetings, direct messaging to healthcare providers, journal articles, and information in the product’s package inserts. ASH would be pleased to work with the FDA to develop a plan to educate hematologists about the final naming convention for biosimilars and other important information about these products.

Thank you for your consideration of ASH’s comments and recommendations. The Society looks forward to continuing to work with you to ensure patient access to safe and effective treatments. Please contact ASH Government Relations and Practice Manager, Stephanie Kaplan (skaplan@hematology.org or 202-776-0544), if we can provide additional information or expertise.

Sincerely,



David A. Williams, MD
President