

March 1, 2014

Elizabeth Jex  
Attorney Advisor  
Office of Policy Planning  
Federal Trade Commission  
600 Pennsylvania Avenue, NW.  
Washington, DC 20580

Dear Ms. Jex,

I am contacting you on behalf of the 17,000 members of the American Academy of Dermatology Association (Academy) to share our thoughts regarding the substitution regulations and naming policies of follow-on biologics. The Academy appreciates the opportunity to provide comments to the Federal Trade Commission (FTC) on this important issue and sincerely hopes that the FTC will take our comments and concerns into consideration as the FTC continues to consider the matter.

The Academy recognizes that this is a highly complex issue, and that the FTC and Food and Drug Administration (FDA) will be balancing the input of a variety of stakeholders who understand the intricacies of biologic development, regulatory policies, and competition to ensure that follow-on biologics are safe, effective, and allow for market competition. The approval of follow-on biologics presents a tremendous opportunity to improve access to these very expensive, but effective, treatment options, which dermatologists often prescribe for psoriasis and other dermatologic diseases. The Academy remains committed to ensuring our patients' safety, while recognizing the importance of access to these effective therapeutics.

### Physician Perspective

The Academy is disappointed that the FTC did not include the physician perspective during the December 10, 2013 workshop on follow-on biologics. Physicians are the primary prescribers of biologics and monitor all adverse events related to these products. Therefore, the physician perspective must be a key consideration in all policy discussions related to follow-on biologics, particularly regarding issues related to state substitution policies and naming policies. While we acknowledge that the FTC is charged with ensuring a fair and competitive market place for follow-on biologics, we urge you to consider the patient-physician partnership as the foundation of all follow-on biologic discussions. Hence, we strongly urge the FTC to include the physician and patient communities in *all* discussions on follow-on biologics.

### Substitution

Patient safety must be of paramount concern as the FTC and FDA move forward in their discussions and policies related to follow-on biologics. Biologic products are highly complex, protein-derived molecules that, by their very nature, cannot be exactly replicated. Due to their variability, a patient's reaction to a follow-on



*American Academy of Dermatology Association*  
Excellence in Dermatology™

1445 New York Ave., NW,  
Suite 800  
Washington, DC 20005-2134

Main: 202.842.3555  
Fax: 202.842.4355  
Website: [www.aad.org](http://www.aad.org)

Dirk M. Elston, MD, FAAD  
*President*

Brett M. Coldiron, MD, FAAD  
*President-Elect*

Lisa A. Garner, MD, FAAD  
*Vice President*

Elise A. Olsen, MD, FAAD  
*Vice President-Elect*

Suzanne Olbricht, MD, FAAD  
*Secretary-Treasurer*

Barbara Mathes, MD, FAAD  
*Assistant Secretary-Treasurer*

Elaine Weiss, JD  
*Executive Director and CEO*

biologic treatment is more uncertain than generic drugs. For this reason, substitution decisions should not be made at the pharmacy level, at least until better comparative data are available. Rather, physicians should be given the sole authority in deciding if a follow-on biologic is an appropriate course of treatment for their patient.

Additionally, communication between pharmacists and physicians is essential to patient safety. Timely notification of a follow-on biologic substitution will allow physicians to monitor patients for potential adverse events due to a substitution in biologic products. Therefore, physician notification at the time of dispensing a follow-on biologic product is imperative to ensure the continuity of patient care. Without proper notification, we fear patient safety will be compromised and physicians will hesitate to prescribe a follow-on biologic products.

### Naming

To protect our patients, the Academy supports assigning follow-on biologics a unique international non-proprietary name (INN). Using the same INN for the follow-on biologic and the reference product will cause unnecessary confusion in the physician and patient community. Patients, physicians, and payers may wrongly conclude that the follow-on biologic and the reference product with the same name are interchangeable products and can be switched throughout the course of treatment. Therapeutic effects, dosing and side effects of the follow-on biologic may differ from the reference product. Therefore, their names and labels should *not* be identical. Instead, a unique INN will curb confusion and ensure that patients receive the correct therapy. A unique INN will also allow regulators and physicians to more easily trace a particular product should an adverse event occur.

For patients suffering from severe psoriasis, psoriatic arthritis, cutaneous lymphomas, inoperable basal cell carcinoma, arthritis, and other serious dermatologic conditions, biologics have provided much needed relief and a greater quality of life. It is our hope that follow-on biologic products will be able to provide the same relief to millions of patients suffering from debilitating skin diseases who are currently unable to afford biologic treatments. The Academy appreciates the opportunity to provide our comments and concerns. Please contact Amanda Grimm, MSHSRA, Senior Specialist, Regulatory Policy, at [agrimm@aad.org](mailto:agrimm@aad.org) or 202-842-3555 should you require any additional information or clarification.

Sincerely,

Dirk Elston, MD  
President, American Academy of Dermatology Association

CC: Mary Maloney, MD, Chair, Regulatory Policy Committee  
Marta Van Beek, MD, Chair, Council on Government Affairs, Health Policy and Practice  
Elaine Weiss, JD, Executive Director  
Barbara Greenan, Senior Director, Government Affairs  
Leslie Stein Lloyd, JD, Director, Regulatory and Payment Policy  
Richard Martin, JD, Assistant Director, Regulatory Policy  
Amanda Grimm, MSHSRA, Manager, Regulatory and Public Policy