Memorandum of Meeting
Patients for Biologics Safety and Access (PBSA)
October 31, 2014, 1:00 to 2:00 pm
White Oak 32 Room 4242

SUBJECT: Meeting with PBSA to listen to their comments and views regarding biosimilars, including views on nonproprietary names of biological products.

PBSA Members

- Virginia Ladd, President and Executive Director American Autoimmune Related Diseases Association
- Sandie Preiss, Vice President, Advocacy & Access Arthritis Foundation
- Amy Kornbluth, Senior Director, Advocacy & Youth Crohn's & Colitis Foundation of America
- Judith Gorsuch, PBSA Consultant Hart Health Strategies
- Larry LaMotte, Vice President, Public Policy Immune Deficiency Foundation
- Johanna Gray, Consultant National Hemophilia Foundation
- Diane Dorman, Vice President, Public Affairs National Organization for Rare Disorders
- Leah McCormick Howard, Director of Government Relations & Advocacy National Psoriasis Foundation
- Alex Bennewith, Vice President, Government Relations United Spinal Association
- Sahrah Buchanan, Consultant HMC US Hereditary Angioedema Association (US HAEA)

Non-PBSA Member

- Mark Fleury, Principal, Policy Development - Emerging Science Cancer Action Network

<u>FDA</u>

- Leah Christl, Associate Director for Therapeutic Biologics, Office of New Drugs, CDER
- Janice Weiner, Senior Regulatory Counsel, Office of Regulatory Policy, CDER
- Maryll Toufanian, Associate Chief Counsel for Drugs, Office of Chief Counsel
- Steven Kozlowski, Director, Office of Biotechnology Products, CDER
- Sarah Crowley-Ikenberry, Health Communication Specialist, CDER
- Cara Tenenbaum, Senior Advisor, Office of Health and Constituent Affairs, OC
- Karen Riley, Deputy Director for Strategy, Office of External Affairs, OC

BACKGROUND:

PBSA reached out to FDA's Office of External Affairs to schedule a meeting to discuss their collective and individual concerns and questions related to biosimilars. PBSA is a coalition of patient advocacy organizations.

To the extent that this discussion involves issues raised by pending citizen petitions related to biosimilars nomenclature, FDA stated that it was open to meeting with PBSA, but it would be a "listening session" (i.e., FDA would be unable to answer questions or expand on any issues beyond what is in the

public domain and what we have stated in the published draft guidance documents). FDA also stated that the minutes for this meeting will be posted in the public dockets for pending citizen petitions related to biosimilars nomenclature.[1]

DISCUSSION SUMMARY:

Each of the meeting participants introduced the focus of their organization, including information about the importance of current treatment with biological products. Meeting participants noted the potential benefits of biosimilar products in terms of expanding access and reducing costs, but also expressed safety concerns about switching between biological products and maintained that prescribing healthcare providers should make such a decision in consultation with their patients.

PBSA shared with FDA its guiding principles, which include that biosimilars should have unique nonproprietary names to eliminate confusion and allow prescribers to accurately track the therapeutic agent in a patient's medical record and quickly trace a product to an adverse event. A meeting participant stated the importance of knowing exactly which product is prescribed and being notified regarding a switch.

PBSA also discussed certain questions related to FDA's biosimilar guidances and shared concerns regarding indication extrapolation.

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[1] See Docket Nos. FDA-2013-P-1153, FDA-2013-P-1398, and FDA-2014-P-0077.