Memorandum of Meeting
Biologics Prescribers Collaborative
December 9, 2014
3:00pm to 4:00pm, White Oak Building 32, Room 4344

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

ATTENDEES:

Biologics Prescribers Collaborative

- David Charles, M.D., Chairman, Alliance for Patient Access
- Gavin Clingham, J.D., Director for Public Policy, Alliance for Patient Access
- Dennis R. Cryer, M.D., FAHA, Chief Medical Officer, CryerHealth, LLC
- Amanda Grimm, Manager of Regulatory and Public Policy, American Academy of Dermatology Association
- Steven Grossman, J.D., HPS Group, LLC
- Joshua Keepes, Director of Regulatory Affairs, American Gastroenterological Association
- Gregory Schimizzi, M.D., Former President, Coalition of State Rheumatology Organizations

FDA

- Zahava Hurwitz, Policy Analyst, Office of Policy
- Leah Christl, Associate Director for Therapeutic Biologics, Office of New Drugs, CDER
- Maryll Toufanian, Associate Chief Counsel for Drugs, Office of Chief Counsel
- Steven Kozlowski, Director, Office of Biotechnology Products, CDER
- Janice Weiner, Senior Regulatory Counsel, Office of Regulatory Policy, CDER
- Cara Tenenbaum, Senior Advisor, Office of External Affairs, OC
- Sarah Ikenberry, Health Communication Specialist, CDER
- Diane Maloney, Associate Director for Policy, CBER
- Anna Fine, Director, Health Professional Liaison Program, Office of Health and Constituent Affairs, OC

BACKGROUND:

The Biologics Prescribers Collaborative requested a meeting with FDA to share their professional perspective on the naming of biologics and biosimilars based on their work in specialty areas in which biologics are frequently prescribed. The Biologics Prescribers Collaborative explained that its members come from a number of specialties—dermatology, rheumatology, gastroenterology, and others—where biologics have transformed the practice of medicine.

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 the Biologics Prescribers Collaborative, 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draft guidance documents).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:

Biologics Prescribers Collaborative (BPC) participants expressed the importance of distinguishable nonproprietary names for biosimilar products. One meeting participant opined that the idea that follow-on biologics could be given the same nonproprietary name was completely unacceptable as one would not know what was dispensed. This BPC participant referenced the WHO proposal for a unique biologic qualifier and noted that the impact of naming is global. Another BPC participant stated the importance of distinguishable nonproprietary names to patients and patient caregivers so that they know what they are receiving.

BPC participants also discussed concerns with substitution (as well as the impact of travel on pharmacy substitution practices) and indication extrapolation.

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