Memorandum of Meeting
GPhA
July 24, 2014
3:30pm to 4:30pm, CR 2102/White Oak Bldg. 1

SUBJECT: Meeting with GPhA to listen to their comments and views regarding nonproprietary names of biological products.

ATTENDEES:

GPhA
David Gaugh, Senior Vice President, Science and Regulatory Affairs, GPhA
Melissa Schulman, Senior Vice President, Government Affairs, GPhA
Chris Davis, Senior Director, Federal Government Affairs, GPhA
John Pakulski, Head, U.S. Biopharmaceutical Regulatory Affairs, Sandoz
Steve Giuli, Director of Government Affairs & Industry Relations, Apotex Corp.
Wendy Sussman, Head, U.S. Government Affairs, Hospira
Lisa Skeens, Corporate Vice President, Global Regulatory Affairs, Hospira
Bruce Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals
Gary Ingenito, Regulatory Affairs Biosimilars, North America, Boehringer-Ingelheim
Jim Luce, Executive Vice President, Sales & Marketing, Amneal Pharmaceuticals
Andrea Miller, Senior Vice President, Global Regulatory Affairs and Drug Safety, Mylan
Martina Bradford, Principal, Bockorny Group

FDA
Sally Howard, Deputy Commissioner for Policy, Planning and Legislation
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
Zahava Hurwitz, Policy Analyst, Office of Policy
Kathleen Burns, Policy Analyst, Office of the Commissioner

BACKGROUND:

GPhA requested this meeting to discuss the biosimilar naming proposal currently under consideration at FDA and HHS. These issues related to a citizen petition[1] submitted by GPhA, which was pending with FDA as of the date of the meeting. FDA stated that it was open to meeting with GPhA, 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answer questions or expand on any issues beyond what is in the public domain and what we have stated in the published draft guidance documents).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.[2] FDA explained that any new information that GPhA would like to have considered in the context of GPhA's pending citizen petition should be submitted to the public docket as a supplement to the petition.

[1] See Docket No. FDA-2013-P-1153.
[2] See also Docket No. FDA-2013-P-1398 and FDA-2014-P-0077.

DISCUSSION SUMMARY:

GPhA stated that naming for biosimilar products should be consistent, simple, and intuitive. GPhA maintains that naming should remain one global process to promote consistency for international patients, providers, and companies.

GPhA discussed current labeling for biological products, which includes several names and identifiers.[3] GPhA maintains that adverse events can be traced back to the biological product through these identifiers without the need for a distinguishable nonproprietary name. GPhA opined that the focus on nonproprietary names deemphasizes the importance of the lot number for a biological product. GPhA further noted that the majority of physicians prescribe by brand name, rather than nonproprietary name. GPhA previously noted its understanding that FDA cannot require sponsors to designate a brand name (proprietary name), and GPhA reiterated that its members would voluntarily commit to use of a brand name for biological products. If FDA determines an additional identifier is necessary, GPhA would be supportive of a proposal that would distinguish between products by attaching the company name as a suffix to the international nonproprietary name (INN) without changing the INN. If an identifier is to be attached to the INN of a biosimilar product, GPhA opined that such an identifier should be attached to the innovator biological product as well (e.g., "filgrastim Amgen"). GPhA stated that if FDA is going to make a change to the current naming convention that they should do so carefully and consider potential unintended consequences. They also recommended that FDA work with prescribing system organizations such as the National Council for Prescription Drug Programs (NCPDP) and others during a transition period to ensure there are no safety implications.

GPhA members discussed their experience with biosimilars approved in the EU, including market uptake and utilization. Independent of naming, they agreed that education and awareness would play a major role in the success of the biosimilars program, and that FDA support would be critical.

ACTION ITEMS/NEXT STEPS:

GPhA may request another meeting with FDA and submit supplemental comments to the citizen petition docket if it has additional comments and views to share.

[3] Brand (proprietary) name, INN/USAN (nonproprietary name), manufacturer, national drug code (NDC) number, and lot number