Memorandum of Meeting
GPhA
January 9, 2014
1:00pm to 1:45pm, CR 1215/White Oak Bldg. 51

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

ATTENDEES:

GPhA
David Gaugh, RPh, Senior Vice President for Sciences and Regulatory Affairs

FDA
Robert Ball, MD, MPH, Deputy Director, Office of Surveillance and Epidemiology, CDER
Ashley Boam, Acting Deputy Director, Office of Pharmaceutical Science, CDER
Leah Christl, PhD, Associate Director for Therapeutic Biologics, OND Therapeutic Biologics and Biosimilars Team (TBBT), OND, CDER
Steven Kozlowski, MD, Director, Office of Biotechnology Products, OPS, CDER
Sue Lim, MD, Senior Staff Fellow, OND Therapeutic Biologics and Biosimilars Team (TBBT), OND, CDER
Yana R. Mille, RPh, Senior Science Policy Advisor, OPS, CDER
Peter Taschenberger, JD, MPH, Regulatory Counsel, Office of Medical Policy Initiatives, OMP, CDER
Maryll Toufanian, JD, Associate Chief Counsel for Drugs
Janice Weiner, JD, MPH, Senior Regulatory Counsel, Office of Regulatory Policy, CDER
Sandra Benton, Senior Policy Analyst, Office of Medical Policy, CDER

BACKGROUND:

GPhA requested this meeting to discuss the dialogue held at a recent World Health Organization (WHO) meeting regarding nonproprietary names of biosimilars and the possible addition of identifiers to the nonproprietary names of innovator biological products to name biosimilar products. These issues relate 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answer questions or expand on any issues beyond what is in the public domain and what we have stated in the published draft guidance documents).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 the position outlined in its September 17, 2013 citizen petition has not changed. GPhA believes that adverse events can be traced back to the biological product involved through the five data points[3] it has outlined previously without the need to change the nonproprietary name. Although it is GPhA's understanding from conversations with individual FDA employees that FDA cannot require sponsors to designate a brand name (proprietary name), GPhA and its members would commit to use of a brand name for biological products.

According to GPhA, at the recent WHO meeting on International Nonproprietary Names (INN), the WHO INN Expert Committee discussed adding a specific identifier to the INN of biosimilar products. This may be the abbreviation BQ (which stands for biologic qualifier) plus 3 random alphanumeric characters. This identifier may be connected to the INN, such as with a hyphen, but would not be considered part of the INN.

GPhA indicated that it is discussing this proposal with its member companies and others, and noted that the random alphanumeric characters of the WHO/INN proposal would not function to directly identify the manufacturer. Accordingly, GPhA also is considering an alternate proposal that would distinguish between products by attaching the company name as a suffix to the 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 believes that this proposal would provide "distinguishable" and "immediate identification." However, GPhA noted its position that this proposal still could have an effect on patient safety, access, and affordability of biological products.

GPhA noted that in the Amgen comment on the GPhA and Novartis citizen petitions and in the recent citizen petition submitted by Johnson and Johnson (J&J), Amgen and J&J assert that the products should have "distinguishability." GPhA stated that it does not disagree with "distinguishability," but believes that this can be done without changing the INN.

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