Memorandum of Meeting
Hospira
August 12, 2014
10:00am to 11:00am, CR 2101/White Oak Bldg. 1

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

ATTENDEES:

Hospira
Wendy Sussman, Head, U.S. Government Affairs, Hospira
Melanie Nathanson, Nathanson+Hauck

FDA
Sally Howard, Deputy Commissioner for Policy, Planning and Legislation
Maryll Toufanian, Associate Chief Counsel for Drugs, Office of Chief Counsel
Leah Christl, Associate Director for Therapeutic Biologics, Office of New Drugs, CDER
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:

Hospira requested this meeting to share its insights with FDA regarding experience in the European, Canadian, and Australian biosimilar markets as the FDA continues with implementation of a biosimilars pathway in the U.S.

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 Hospira, 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answer questions or expand on any issues beyond what is in the public domain and what we have stated in the published draft guidance documents).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:

Hospira stated that mandating use of the brand name as a unique identifier for biosimilar products is of great interest to Hospira.

Hospira discussed its view that the international nonproprietary name (INN) for a biosimilar product should be the same as the reference product, but the brand name could be used as a unique identifier that is not attached to the INN. Hospira explained that the brand qualifier would only be used for pharmacovigilance, and would not be carried into biological product ordering systems. Hospira noted

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

that if the brand name becomes the unique identifier, then products are trackable because physicians are writing prescriptions using the brand name. If a physician wrote a prescription using the INN, Hospira opined that the intended product would be understood based on its formulary placement.

Hospira also discussed their experience in the European, Canadian, and Australian biosimilars markets, and issues related to education and reimbursement.

ACTION ITEMS/NEXT STEPS:

Hospira may request another meeting with FDA if it has additional comments and views to share.