Memorandum of Meeting
Express Scripts
December 9, 2013
1:00pm to 2:00pm, CR 2101/White Oak Bldg. 1

SUBJECT: Meeting with Express Scripts to listen to their comments and views on biosimilars and other related issues.

ATTENDEES:

Express Scripts
Dr. Steve Miller, MD, MBA, Senior Vice President and Chief Medical Officer
Jonah Houts, Vice President, Government Affairs
Everett Neville, Chief, Pharma Supply Chain
Mary Rosado, Vice President, Federal Affairs

FDA
Sally Howard, Deputy Commissioner for Policy, Planning and Legislation, OC
Patrick Archdeacon, MD, Senior Clinical Advisor, Office of Medical Policy, CDER
Sandra Benton, Senior Policy Analyst, Office of Medical Policy, CDER
Zahava Hurwitz, Policy Analyst, Office of Policy, OC
Rachel Sherman, MD, Associate Director for Medical Policy, CDER
Maryll Toufanian, JD, Associate Chief Counsel for Drugs
Janice Weiner, JD, MPH, Senior Regulatory Counsel, Office of Regulatory Policy, CDER

BACKGROUND:

Express Scripts requested this meeting to discuss their comments and views on biosimilars and other related issues. Some of these issues relate to citizen petitions on biosimilar naming,[1] which were pending with FDA as of the date of the meeting. FDA stated that it was open to meeting with Express Script, 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answer questions or expand on any issues beyond what is in the public domain and what we have stated in the published draft guidance documents).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] See Docket Nos. FDA-2013-P-1153 and FDA-2013-P-1398.

DISCUSSION SUMMARY:

Express Scripts shared its presentation for the December 10, 2013, FTC Public Workshop on Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition (rescheduled to February 4, 2014).[2]

Express Scripts stated that its position is the same as that submitted in comments to the dockets of the two public hearings (November 2010 and May 2012) and the guidance documents published in 2012. Express Scripts does not believe that unique nonproprietary names are necessary for biosimilar and interchangeable biological products. Rather, the company believes that biosimilar and interchangeable biological products can be tracked by the National Drug Code (NDC), which already is captured for reimbursement in outpatient pharmacies, and required under Medicaid.

Express Scripts noted that it had reviewed its systems regarding 11 biological products that could eventually be developed into biosimilars. The company represented that it could track these products, especially when dispensed through an outpatient pharmacy. If a product was dispensed in another setting, such as epoetin in a dialysis clinic, Express Scripts believes that these institutions would be able to identify the product dispensed in their records based on the lot number.

The company expressed concerns that unique names would negatively impact market penetration of biosimilars because different names may cause healthcare practitioner confusion and undermine interchangeable biological products and substitution. The company represented that savings will come from increased access to these products. Express Scripts also believes there is a broad misconception that if a biosimilar product is licensed, substitution will occur automatically; the company noted that this would not occur under current state pharmacy substitution laws.

[2] http://www.ftc.gov/news-events/events-calendar/2014/02/follow-biologics-workshop-impact-recent-legislative-regulatory