Memorandum of Meeting
American Medical Association
July 9, 2014
11:00am to 12:00pm, White Oak Bldg 31, Rm. 3502

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

ATTENDEES:

American Medical Association (AMA)

- Sandy Marks, Assistant Director, Federal Affairs
- Sylvia Trujillo, Legislative Counsel
- Cybil Roehrenbeck, Assistant Director, Division of Federal Affairs
- Barry D. Dickinson, PhD Director, Science and Biotechnology & Secretary, Council on Science and Public Health (*via Phone*)
- Daniel Blaney-Koen, Senior Legislative Attorney (*via Phone*)

Food and Drug Administration (FDA)

Office of the Commissioner (OC)

- Anna Fine, Director, Health Professional Liaison Program, OHCA
- Danielle Grote, Acting Director of Intergovernmental Affairs, Office of Policy, Planning and Legislation (OPPL)
- Zahava Hurwitz, Policy Analyst, Office of Policy
- Steven Immergut, Associate Commissioner for External Affairs
- Catherine Lorraine, Director, Policy Development and Coordination Staff, Office of Policy
- Heidi Marchand, Assistant Commissioner, Office of Health and Constituent Affairs (OHCA)
- Elisabeth Newcomb, Staff Fellow, Office of Planning, Economics Staff
- Christopher Pruitt, Associate Chief Counsel for Drugs, Office of Chief Counsel
- Karen Riley, Deputy Director for Strategy, Office of External Affairs (OEA)
- Cara Tenenbaum, Senior Advisor, Office of Health and Constituent Affairs (OHCA)
- Maryll Toufanian, Associate Chief Counsel for Drugs, Office of Chief Council

Center for Drug Evaluation and Research (CDER)

- Sandra Benton, Senior Policy Analyst, Office of Medical Policy (OMP)
- Steven Kozlowski, Director, Office of Biotechnology Products
- Janice Weiner, Senior Regulatory Counsel, Office of Regulatory Policy

Center for Biologics Evaluation and Research (CBER)

- Diane Maloney, Associate Director for Policy

Europeans Medicine Agency (EMA)

- Sabine Haubenreisser, European Medicines Agency liaison official at the US Food and Drug Administration

BACKGROUND:

The AMA requested a meeting with FDA to discuss feedback from its membership regarding biosimilars and the need for provider education on the topic.

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 AMA, 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:

The AMA discussed its Report of the Council on Science and Public Health regarding biosimilar product approval and marketing. The AMA noted that it did not take a specific position regarding naming, but described various considerations. AMA opined that potential influences on biological product naming include prescribing healthcare provider attitudes, pharmacovigilance, and international harmonization. The AMA explained that some medical specialty groups have taken a position in favor of unique nonproprietary names, but noted that surveys are highly influenced by the questions asked and the respondent's level of knowledge. The AMA indicated that physician education about the biosimilar product approval pathway is needed.

The AMA also discussed physician attitudes regarding substitution, various state legislative activities, and opportunities for public/provider education regarding biological products. The AMA also suggested that FDA compile an official compendium for biosimilars that is like the "Orange Book."

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