Memorandum of Meeting
April 11, 2019
10:00am to 11:00am, CR 1448/White Oak Bldg. 75

SUBJECT: Listening Meeting with Dr. Sarfaraz Niazi regarding biosimilars

ATTENDEES:

Sarfaraz K. Niazi, PhD, College of Pharmacy, University of Illinois at Chicago

FDA
Peter Stein, MD, Director, Office of New Drugs, CDER
Sarah Yim, MD, Acting Director, Office of Therapeutic Biologics and Biosimilars, OND, CDER
Sandra Benton, Senior Policy Coordinator, Office of Therapeutic Biologics and Biosimilars, OND, CDER

FDA granted the request made on March 25, 2019, by Dr. Sarfaraz K. Niazi for a meeting, noting that the meeting would be a listening meeting only. Dr. Niazi provided a document entitled "Risk-Based Licensing of Biosimilars" prior to the meeting. During the listening meeting, which was held on April 11, 2019, FDA asked clarifying questions about Dr. Niazi's presentation but did not provide comments or answer questions. Dr. Niazi provided FDA with an updated version of this document after the meeting. The content of Dr. Niazi's presentation was substantially similar to the content of these documents.

Dr. Niazi submitted the updated version of the document entitled "Risk-Based Licensing of Biosimilars" to the docket associated with one of Dr. Niazi's currently pending citizen petitions regarding the regulation of biosimilars (*see* Docket No. FDA-2019-P-1236-0003). Dr. Niazi titled his submission "Testimony from Sarfaraz Niazi" and described its content as "Minutes of Meeting between Sarfaraz Niazi and the FDA held on 12 April 2019 to discuss revisions to biosimilars evaluation guidance." We note that the meeting was actually held on April 11, 2019 and did not constitute "testimony" as that term is ordinarily understood.

FDA has added the originally submitted version of the document entitled "Risk-Based Licensing of Biosimilars" to Docket No. FDA-2019-P-1236. Also, because the positions advanced by Dr. Niazi in both versions of this document and his April 11 presentation overlaps, in part, with the actions requested in Dr. Niazi's other pending citizen petition regarding biosimilars (Docket No. FDA-2018-P-1876), FDA has also added both versions of the document and this memorandum to that docket as well.

Attachments