DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

JUN 17 2016

William W. Chin, M.D.
Executive Vice President
Scientific and Regulatory Affairs
Pharmaceutical Research and Manufacturers of America
1201 Maryland Avenue, SW, Suite 900
Washington, DC 20024

Kay Holcombe
Senior Vice President for Health Policy
Biotechnology Industry Organization
950 F Street, NW, Suite 300
Washington, DC 20004

Re: Docket No. FDA-2015-P-5022

Dear Dr. Chin and Ms. Holcombe:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received December 22, 2015, and submitted on behalf of the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization. Your petition requests that FDA require that the approved prescription drug labeling for biosimilar biological products state the product has been approved as a biosimilar for stated indications and routes of administration and identify the reference product, describe the basis of approval for each indication by identifying the relevant data for the reference product and biosimilar that support a finding of biosimilarity, and state whether or not FDA has made a determination of interchangeability with the reference product and include any such FDA finding.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your requests.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research