DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY 19 2016

Meredith Miller
Chief Corporate Governance Officer
UAW Retiree Medical Benefits Trust
P.O. Box 14309
Detroit, MI 48214

Re: Docket No. FDA-2015-P-4529

Dear Ms. Miller:

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 November 24, 2015, and submitted on behalf of a group of institutional investors including the United Auto Workers Retiree Medical Benefits Trust. Your petition requests that FDA require that all approved prescription drug labeling for biosimilar and interchangeable biological products follow the "same labeling" approach that, according to your citizen petition, the Agency applied to Zarxio, and hold a Part 15 public hearing on this issue as well as any other related issues being debated by the FDA and connected to biosimilars.

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