U.S. FOOD & DRUG ADMINISTRATION

Michael A. Carome M.D., et al.
Public Citizen
1600 20th Street, NW
Washington, DC 20009

MAY 11 2018

Re: Docket No. FDA-2017-P-6513

Dear Dr. Carome:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on November 15, 2017, and submitted on behalf of Public Citizen and Public Citizen's Health Research Group. Your petition requests that the Agency immediately remove from the market all medications containing olmesartan medoxomil, including medications branded as Azor, Benicar, Benicar HCT, and Tribenzor, as well as all generic versions of these drugs.

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 request.

Sincerely,

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