DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 15, 2017

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

Sent via email to: mcarome@citizen.org

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug immediately require the removal from the market of all medications containing olmesartan medoxomil, including medications branded as Azor, Benicar, Benicar HCT, and Tribenzor, as well as all generic versions of these drugs was received by this office on 11/15/2017.

It was assigned docket number FDA-2017-P-6513. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)