U.S. FOOD & DRUG ADMINISTRATION

David Light, CEO
Kaury Kucera, Ph.D., Chief Scientific Officer
Valisure, LLC
5 Science Park
New Haven, CT 06511

Re: Docket No. FDA-2019-P-2869

JAN 0 2 2020

Dear Mr. Light and Dr. Kucera:

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 on June 13, 2019. Your petition requests that the Agency take the following actions:

1) Review and significantly lower the acceptable intake/permitted daily exposure (PDE) limit of DMF;
2) Request a recall of identified lots of valsartan on the basis that these drugs are adulterated and misbranded because they have been contaminated with a probable human carcinogen;
3) Conduct examinations and investigations regarding these products, their manufacturing processes, and the manufacturer's submissions for FDA approval and require labeling changes as needed;
4) Provide information to the public regarding these products; and
5) Promulgate regulations requiring robust independent chemical batch-level testing and verification of the chemical content of batches of pharmaceuticals of drugs, and issue guidance recommending testing and verification, while these regulations are pending.

FDA has been unable to reach a decision on your petition due to the need to address other agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov