DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 13, 2019

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

Sent via email to: info@valisure.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to take the following actions:

1. review and significantly lower the acceptable intake/permitted daily exposure limit of DMF, as listed in the current FDA guidance Q3C – Tables and List, Guidance for Industry, from its current level of 8,800,000 nanograms to less than 1,000 nanograms (and potentially as low as 96 nanograms);

2. request a recall of identified lots of valsartan on the basis that, due to contamination with a probable human carcinogen, these drugs are adulterated under Section 501 of the FDCA (21 U.S.C. § 351) and misbranded under Section 502 of the FDCA (21 U.S.C. § 352);

3. conduct examinations and investigation under Section 702 (a) of the FDCA (21 U.S.C. § 372(a)) regarding these products, their manufacturing processes, and the manufacturer submissions made for FDA approval under 704 (a)of the FDCA (21 U.S.C. § 374(a)) and effect labeling revisions as needed;

4. provide information to the public regarding these products under Section 705(b) of the FDCA (21 U.S.C. § 375(b)); and

5. promulgate regulations requiring robust independent chemical batch-level testing and verification of the chemical content of batches of pharmaceuticals of drugs and, while these regulations are pending, issue guidance requesting such testing and verification.

Your submission was received by this office on 06/13/2019. It was assigned docket number FDA-2019-P-2869. 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2019.06.13 14:01:42 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)