March 18, 2020

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-4281

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

1) Request a recall and suspend sale of all lots of all products containing ranitidine. The drug should be recalled because it contains a carcinogen and is misbranded under section 502 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 USC 352);
2) Conduct examinations and investigation regarding these products, their manufacturing processes, and the manufacturer submissions under section 704(a) of the FD&C Act;
3) Provide information to the public regarding these products under section 705(b) of the FD&C Act;
4) Provide guidance to the public for the safe disposal of ranitidine given the potential degradation of ranitidine to form NDMA in the water supply; and
5) Promulgate regulations requiring independent chemical testing and verification of pharmaceuticals, and while these regulations are pending, issue guidance requesting such testing and verification.

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 Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.03.17 16:43:34 -04'00'

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