



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 13, 2019

David Light
Valisure, LLC
Chief Executive Officer
5 Science Park
New Haven, CT 06511

Sent via email to: david.light@valisure.com

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting to issue a regulation, revise industry guidance, and request a recall and suspend sales of ranitidine from the US market and take such other actions listed in the petition was received by this office on 09/13/2019.

It was assigned docket number FDA-2019-P-4281. 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
Dockets Management Staff
FDA/Office of Operations (OO)