



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

March 2, 2020

David Light, CEO
Kaury Kucera, Ph.D., CSO
Qian Wu, Ph.D., Director, Mass Spectrometry
Valisure, LLC
5 Science Park
New Haven, CT 06511

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

Dear Petitioner:

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

1. request a recall of identified batches of metformin 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);
2. 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;
3. provide information to the public regarding these products under Section 705(b) of the FDCA (21 U.S.C. § 375(b));
4. update and revise FDA guidance document FY20-058-DPA-S, to include the analytical methodology outlined in this petition and in Attachment A for improved quantitation of NDMA in metformin and to avoid underestimation of NDMA levels;
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 03/02/2020, and it was assigned docket number FDA-2020-P-0978. 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 Officer
Dockets Management Staff
FDA/Office of Operations (OO)