David Light/Wolfgang Hinz/Kaury Kucera
Valisure LLC
5 Science Park
New Haven, CT 06511

August 28, 2024

Re: Docket No. FDA-2024-P-1130

Dear Petitioners:

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 March 5, 2024 (Petition). Your petition asserts that Valisure has tested and detected "high levels of benzene in many specific batches of [benzoyl peroxide] products" and states that "the current evidence suggests that on-market [benzoyl peroxide] products could produce substantial amounts of benzene when stored at above-ambient temperatures" (Petition at 1). The Petition requests that FDA take the following actions to address these issues:

1) request a recall and suspension of sale of products containing benzoyl peroxide;

2) conduct examinations and investigation under section 702 (a) of the Federal Food, Drug and Cosmetic Act (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));

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

4) develop guidance documents for the analysis of benzene in benzoyl peroxide products;

5) review and update the current FDA guidance "Q3C – Tables and List, Guidance for Industry" to include guidance for the acceptable concentration of benzene for drug products, such as benzoyl peroxide-containing products, that do not require benzene for manufacturing and do not constitute a "significant therapeutic advance," or potentially expand the current statement that benzene "should not be employed in the manufacture of drug substances" to clarify that there is no acceptable level of benzene and define a reasonable limit of detection;

6) review and update the current FDA guidance "Q3C – Tables and List, Guidance for Industry" to include guidance on the permitted daily exposure of benzene for drug products that do not require benzene for manufacturing and do not constitute a "significant therapeutic advance" and separately for drug products that require benzene for manufacturing and constitute a "significant therapeutic advance";

7) consider working with the United States Environmental Protection Agency on a joint initiative to address benzene contamination and potentially enter into a formal agreement committing to increase collaboration and coordination in areas of mutual interest relating to benzene contamination;

8) support the increasing number of independent drug quality testing programs in the United States (including by the US Department of Defense) by convening workshops, stakeholder meetings and providing other resources at FDA's disposal to further encourage and connect such programs; and

9) promulgate regulations requiring robust independent chemical batch-level 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
Date: 2024.08.28 13:01:52 -04'00'

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