U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

March 29, 2023

David Light
Qian Wu
Valisure, LLC
5 Science Park
New Haven, CT 06511

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

Re: Docket Number FDA-2022-P-2707

Dear Petitioners:

This responds to your citizen petition dated October 31, 2022, under docket number FDA-2022-P-2707 requesting that the Food and Drug Administration (FDA or we) take the following actions:

1. request a recall of identified batches of dry shampoo cosmetic products on the basis that, due to contamination with a known human carcinogen, these products are adulterated under Section 601 of the FDCA (21 U.S.C. § 361) and misbranded under Section 602 (21 U.S.C. § 362);

2. review and update regulations and published guidance for cosmetic products to include limitations on various impurities that pose known risks to human health and include benzene in such updates, and potentially include clarification that there is no acceptable level of benzene in cosmetic products and establish a reasonable detection limit;

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 dry shampoo products;

5. develop guidance documents defining the mass of a standard daily total application of dry shampoo, which may include multiple discrete applications, so that a daily exposure of benzene can be calculated for dry shampoo products;

6. 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;

7. support the increasing number of independent quality testing programs in the United States by convening workshops, stakeholder meetings and providing other resources at FDA's disposal to further encourage and connect such programs; and

8. promulgate rules or administrative orders requiring robust independent chemical batch-level testing and verification of the chemical content of batches of regulated consumer products and, while these are pending, issue guidance requesting such testing and verification.

The purpose of this response is to advise you, in accordance with 21 CFR 10.30(e)(2), that we have not reached a decision on your petition within the first 180 days of filing the citizen petition due to a number of competing priorities. However, please be advised that our staff is evaluating your petition.

Sincerely,

Linda M. Katz -S

Digitally signed by Linda M. Katz -S
Date: 2023.03.30 13:33:00 -04'00'

Linda M. Katz, M.D., M.P.H.
Director
Office of Cosmetics and Colors
Center for Food Safety and Applied Nutrition