November 1, 2022

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

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

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug 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.

Your petition was received and processed under CFR 10.30 by this office on 10/31/2022. It was assigned docket number FDA-2022-P-2707. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.11.01 11:23:41 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)

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