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February 13, 2025

Re: Docket No. FDA-2024-P-3997

Dear Petitioner:

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 August 20, 2024 (Petition). Your petition asserts that you have acquired and had tested numerous benzoyl peroxide acne treatment products and found that these products contain “dangerous” levels of benzene (Petition at 2). Your petition requests that FDA therefore recall and suspend sales of benzoyl peroxide from the U.S. market.

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.¹

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett

Date: 2025.02.13 09:59:47 -05'00'

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

¹ Your Petition offers to provide the Agency with copies of tests described in the Petition (Petition at footnote 3). We have sent several requests that you submit the tests described to the Agency. To date, no copies of the testing have been submitted.