U.S. FOOD & DRUG ADMINISTRATION

Alan G. Minsk
Kadeja A. Watts
Arnall Golden Gregory LLP
171 17th Street, N.W., Suite 2100
Atlanta, GA 30363

September 26, 2022

Re: Docket No. FDA-2022-P-0509

Dear Mr. Minsk and Ms. Watts:

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 31, 2022. Your petition requests that the Agency "establish new science-based limits to control for 2-methyl-3-phenylaziridine in amphetamine salts APIs" and recommends "that it be controlled to less than 0.01 percent" (Petition at 1).

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: 2022.09.26 10:09:46 -04'00'

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

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