Ayesha Ahmed, General Counsel
Nexus Pharmaceuticals, Inc.
400 Knightsbridge Parkway
Lincolnshire, Illinois 60069

May 25, 2023

Re: Docket No. FDA-2022-P-2998

Dear Ms. Ahmed,

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 November 23, 2022 and submitted on behalf of Nexus Pharmaceuticals, Inc. Your petition requests that the Agency:

(1) Issue a Final Notice in the *Federal Register* excluding ephedrine sulfate from the list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act.

(2) Issue a Final Notice in the *Federal Register* rescinding the *Interim Policy on Compounding Bulk Drug Substances Under 503B of the Federal Food, Drug, and Cosmetic Act* (January 2017).

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: 2023.05.24 11:25:28 -04'00'

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

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