November 23, 2022

Ayesha Ahmed, General Counsel
Nexus Pharmaceutical Inc.
400 Knightsbridge Parkway
Lincolnshire, IL 60069

Sent via email to: aahmed@nexuspharma.net

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drugs take the actions set forth below with respect to the compounding of bulk drug substances, including ephedrine sulfate, by outsourcing facilities and for the reasons explained in more detail below take each of the following actions within 180 days of the date of this petition.

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 ("FDCA") ("503B Bulks List").

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) ("503B Interim Policy").

This petition was received and processed under CFR 10.30 by this office on 11/23/2022.

It was assigned docket number FDA-2022-P-2998. 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,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.11.25 09:43:10 -05'00'

Dynna Bigby
Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)