June 9, 2022

Sheldon Bradshaw
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Washington, DC 20006-4707

Sent via email to: sbradshaw@kslaw.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug:

1. Determine, based on current drug approval standards, that the Sodium Thiosulfate Injection drug product approved under New Drug Application ("NDA") #020166 was withdrawn from sale for reasons of safety or effectiveness; and

2. Refrain from receiving or approving any Abbreviated New Drug Application ("ANDA") submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") that identifies the Sodium Thiosulfate Injection drug product approved under NDA #020166 as the reference listed drug ("RLD").

Your petition was received and processed under CFR 10.30 & 10.35 by this office on 06/08/2022 and assigned docket number FDA-2022-P-1080. 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: 2022.06.09 12:03:07 -04'00'

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