Sheldon Bradshaw
King & Spalding LLP
1700 Pennsylvania Ave., NW, Suite 900
Washington, DC 20006

November 4, 2022

Re: Docket No. FDA-2022-P-1080

Dear Mr. Bradshaw:

This letter responds to your petition dated June 7, 2022 (Petition).[1] The Petition requests that the U.S. Food and Drug and Administration (FDA or the Agency):

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standards, that the Sodium Thiosulfate Injection drug product approved under New Drug Application ("NDA") #020166 was withdrawn from sale for reasons of safety or effectiveness; and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

For the reasons described below, FDA denies the Petition without substantive evaluation.

I. DISCUSSION

Under FDA's regulations at 21 CFR 10.31, any petition that requests that the Commissioner take any form of action that could, if taken, delay approval of an ANDA must include the following certification:

> I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____[in the blank space, provide the date on which such information first became known to the person submitting the petition]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

[1] We attempted to contact you by email on August 16, 2022, and September 20, 2022, regarding the Petition and the certification described further below, but we did not receive a response to these prior communications.

Your Petition explicitly requests that FDA refrain from receiving or approving an ANDA that identifies NDA 020166 as its RLD. In doing so, the Petition necessarily seeks to prevent or delay approval of any ANDA with NDA 020166 as its basis of submission, and accordingly, falls within the scope of 21 CFR 10.31. FDA will not consider your Petition for review unless it contains the complete certification described in 21 CFR 10.31(c).[2] Your Petition is deficient because it does not contain the complete certification. Specifically, the language of your certification does not exactly mirror the language provided in 21 CFR 10.31(c), and the date provided does not satisfy the month, day, and year requirement.[3]

We thus deny your Petition under 21 CFR 10.31(c), without evaluating the claims and information contained in the Petition. If you would like FDA to consider such information and to evaluate your claims, please submit a new citizen petition under 21 CFR 10.30 and include the complete certification described in 21 CFR 10.31(c).

II. CONCLUSION

For the reasons described, the Agency denies your Petition.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2022.11.04 11:47:23 -

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[2] 21 CFR 10.31(c). *See* FDA's Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (September, 2019) ("505(q) Guidance").

[3] 21 CFR 10.31(c). *See* 505(q) Guidance, at 11.