March 23, 2022

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Sent via email to: sbradshaw@kslaw.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine under 21 C.F.R. §314.16l(a)(3) that Sodium Thiosulfate Injection (NOA #020166), which was discontinued in 2004, was withdrawn from sale for reasons of safety or effectiveness. Importantly, FDA may make such a determination based on current standards and the availability of other drugs in the marketplace, even if the Agency would not have made the same determination in 2004 when NOA #020166 was discontinued by the U.S. Army. Drug products that FDA determines were withdrawn from sale for safety or effectiveness reasons are removed as "listed drugs" (or RLDs) from the FDA publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations* (known as the *"Orange Boole')* under 21 C.F.R. § 3 l 4. l 62(a)(2). This Citizen Petition therefore requests further that FDA remove NOA #020166 as a listed drug from the *Orange Book* and refrain from receiving or approving any ANDA that identifies Sodium Thiosulfate Injection (NOA #020166) as the RLD.

This Citizen Petition was received and processed under CFR 10.30 by this office on 03/22/2022. It was assigned docket number FDA-2022-P-0414. 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: 2022.03.24 22:23:41 -04'00'

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