

June 8, 2022

Richard O. Wood The Wood Burditt Group LLC 10 E. Scranton Ave., Suite 201 Lake Bluff, IL 60044

Sent via email to: rowoo@woodburditt.com

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug to provide a determination that 0.9% Sodium Chloride Irrigation USP, with a 1250 mL (1.25 L) fill volume in a 2L flexible plastic container (change in strength), is suitable for submission in an Abbreviated New Drug Application was received and processed under CFR 10.30 by this office on 06/07/2022.

It was assigned docket number FDA-2022-P-1060. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability 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 Malvin Acting Director Dockets Management Staff FDA/Office of Operations (OO)