

May 25, 2022

Nancy E. Taylor Greenberg Traurig 2101 L. Street, N.W., Suite 1000 Washington, DC 20037

Sent via email to: taylorn@gtlaw.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug to issue the administrative order for the OTC external analgesics as deemed final by section 505G of the FD&C Act, and that the FDA confirm and clarify for which specific indications OTC external analgesic drug products in PPP dosage forms are generally recognized as safe and effective was received and processed under CFR 10.30 by this office on 05/24/2022.

It was assigned docket number FDA-2022-P-0896. 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 Malvin Acting Director Dockets Management Staff FDA/Office of Operations (OO)