U.S. FOOD & DRUG ADMINISTRATION

Nancy E. Taylor, Esq.
Greenberg Traurig
2101 L Street NW, Suite 1000
Washington, DC 20037

November 17, 2022

Re: Docket No. FDA-2022-P-0896

Dear Ms. Taylor:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on May 24, 2022. Your petition requests that FDA issue the administrative order for Over-the-Counter (OTC) external analgesics as deemed final by section 505G of the Federal Food, Drug & Cosmetic Act (FD&C Act), and that in the order FDA confirm and clarify for which specific indications OTC external analgesic drug products in patch, plaster, or poultice (PPP) dosage forms are generally recognized as safe and effective (GRASE) (e.g., mild backpain or backache). The petition also requests that FDA further confirm and clarify in the order that submission of an application under FD&C Act section 505(b), 505(j), or potentially 505G is warranted for other indications and that the labeling of OTC external analgesic drug products in PPP dosage forms must be limited to those specific indications and claims for which there is sufficient data demonstrating that the active ingredient and PPP dosage form combination is safe and effective.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

David Joy -S

Digitally signed by David Joy -S
Date: 2022.11.17 09:24:09 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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