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August 10, 2022

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: Citizen Petition from Greenberg Traurig requesting that FDA issue the administrative order for OTC external analgesics, and that FDA confirm and clarify for which specific indications OTC external analgesic drug products in patch/plaster/poultice dosage forms are generally recognized as safe and effective (Docket No. FDA-2022-P-0896).**

The Consumer Healthcare Products Association (CHPA)[1] appreciates the opportunity to provide feedback on the May 24, 2022, Citizen Petition from Greenberg Traurig. The Petition "*…requests that the FDA issue the administrative order for OTC external analgesics as deemed final by section 505G of the FD&C Act, and that in the order FDA confirm and clarify for which specific indications OTC external analgesic drug products in PPP [patch, plaster, or poultice] dosage forms are generally recognized as safe and effective (GRASE) (e.g., mild backpain or backache), and that the 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*."

## Regulatory History of External Analgesic Ingredients, Indications, and Dosage Forms Under the OTC Monograph

In 1983, FDA published the Tentative Final Monograph (TFM) for External Analgesic Drug Products (48 FR 5852-5869, February 8, 1983), proposing a number of active ingredients including methyl salicylate, menthol, capsaicin, and camphor ("in a form suitable for topical administration", *e.g.*, creams, lotions, ointments) as Category I (generally recognized as safe and effective). This designation occurred subsequent to an expert panel[2] review of the ingredients.[3] Following a review, the Agency concurred with the Panel's recommendation.

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy.
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[2] Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products

[3] External Analgesic Drug Products for Over-the-Counter Human Use; Establishment of a Monograph and Notice of Proposed Rulemaking. Fed. Reg. 44(234): 69768-69866, December 4, 1979

Patch/plaster/poultice dosage forms were designated Category III in a 2003 proposed amendment to the external analgesics TFM (68 FR 42324-42327, July 17, 2003). In an October 2003 submission to FDA, the CHPA External Analgesic Task Group presented a proposed testing program, using in vitro and in vivo methods, to confirm the safe concentrations of ingredients applied in patches or other novel dosage forms and to show adequate dose delivery for effectiveness. FDA did not provide a response to the CHPA External Analgesic Task Group's proposal.

**CHPA Response to Petitioners Claims**

In reference to the Petitioners concerns that FDA may consider OTC external analgesic patches as effective in treating chronic pain,[4] CHPA notes that ingredients marketed under the External Analgesic Drug Products Monograph are clearly indicated for the temporary treatment of pain as described in the 1983 TFM.

In the preamble to the 1983 TFM FDA states:

> "*The agency concurs with the Panel that the indications for OTC external analgesic drug products should emphasize that these products relieve only minor pain and have an action that is only temporary*."

The indications provided in the 1983 TFM for External Analgesic Drug Products consisted of the following:

For analgesic, anesthetic, and antipruritic active ingredients (e.g., lidocaine, camphor, menthol)

> "For the temporary relief of "(select one of the following: "pain," "itching," or "pain and itching") (which may be followed by: "associated with" (select one or more of the following: "minor burns," "sunburn," "minor cuts," "scrapes," "insect bites," or "minor skin irritations."))

For counterirritant active ingredients (e.g., methyl salicylate, menthol, camphor, capsaicin)

> "For the temporary relief of minor aches and pains of muscles and joints" [which may be followed by: "associated with" (select one or more of the following: "simple backache," "arthritis," "strains," "bruises," and "sprains.")]

[4] "*If entire classes of non-opioid analgesics, such as external analgesic in PPP dosage form, were declared by FDA as generally recognized as safe and effective for managing acute or chronic pain or specific pain indications, without sufficient evidence of such, it would likely severely undercut future efforts to encourage the development of data that may demonstrate the safety and effectiveness of external analgesic in PPP dosage form for managing acute, chronic, and specific pain indications*."

In addition, the required warning for all ingredients consists of the following:

> "If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a "(select one of the following: "physician" or "doctor").

The Petitioners' request that FDA clarify the specific indications for which OTC external analgesic patches are GRASE should be denied. As noted above, currently marketed ingredients regulated under the External Analgesic Drug Products Monograph are designated Category I. Demonstration that external analgesic ingredients administered topically via a patch have a comparable dermal absorption profile (tested by validated methods) to similarly formulated[5] dosage forms recognized under the Monograph (creams, lotions, or ointments) should be sufficient to substantiate GRASE recognition for patches.[6] The safety of external analgesic ingredients delivered via the patch dosage form is supported by previous CHPA submissions[7] demonstrating a very low rate of manufacturer reported adverse events.

Rather than responding to this Citizen Petition, CHPA recommends FDA follow the processes established under the OTC Monograph User Fee Act of 2020 (OMUFA). Under this new process, FDA can update rules for OTC drug products regulated under the Monograph system. We encourage FDA to notify stakeholders of any proposed changes to the current monograph for External Analgesic Drug Products via publication within the 'Annual Forecast for Planned Monograph Activities', a nonbinding list of planned monograph activities that FDA intends to address over the ensuing 3 years.

In addition, a public facing web-portal, OTC Monographs@FDA, allows stakeholders and the public to view OTC monographs and proposed and final administrative orders adding, removing, or changing conditions for an OTC monograph. The current structure thus allows FDA to issue a Proposed Administrative Order calling for data on dosage forms previously designated Category III.

[5] Similarly formulated in terms of active ingredient composition and concentration.
[6] Similar to ingredients delivered via oral dosage forms (*e.g.*, tablet, capsule, soft gel, *etc*).
[7] CHPA submissions to FDA Docket No. 78N-0301 External Analgesic Drug Products for Over-the-Counter Human Use dated October 15, 2003; February 16, 2010; and February 27, 2012.

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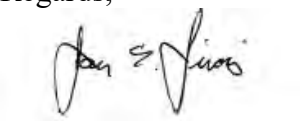
CHPA and our member companies appreciate the opportunity to comment on this Petition. Should you have any questions, please do not hesitate to contact me.

Regards,



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