



United States of America
FEDERAL TRADE COMMISSION
Washington, DC 20580

Division of Advertising Practices

May 13, 2014

VIA ELECTRONIC MAIL

Andrea C. Levine
Senior Vice President, Director
National Advertising Division
112 Madison Avenue, 3rd Floor
New York, NY 10016

Dear Ms. Levine:

I write to inform you of the results of our review into the advertising for the Salonpas Pain Relief Patch, the Salonpas Arthritis Pain Patch, and the Salonpas Gel Patch Hot. The National Advertising Division (“NAD”) referred this matter to the Federal Trade Commission after Hisamitsu Pharmaceutical, Inc. (“Hisamitsu”) declined to participate in an NAD review of its advertising based on a challenge brought by Pfizer Consumer Healthcare (“Pfizer”), the maker of ThermaCare Heatwraps. The core of Pfizer’s challenge is that Hisamitsu advertises in a misleading way the literally true fact that the Salonpas Pain Relief Patch and Arthritis Pain Patch are the only over-the-counter (“OTC”) medicated patches approved by FDA to relieve mild to moderate pain for up to twelve hours.¹

After reviewing this matter, we have determined not to recommend enforcement action at this time. As you know, our approach in all advertising cases is to first analyze the net impression created by the statements, graphics, and other depictions used in the advertising. We then look to whether the advertiser has a “reasonable basis” for its objective product claims. In this case, absent extrinsic evidence to the contrary, we do not believe that the overall net impression of Hisamitsu’s advertisements is misleading.

¹ In declining to participate, Hisamitsu argued that the “FDA Approval,” “mild to moderate pain,” and “up to 12 hours” effectiveness claims were not within NAD’s mandate, as they were “expressly approved by federal law or regulation” by virtue of FDA’s approval of the new drug application for the Salonpas Pain Relief Patch and Arthritis Pain Patch. In its decision, NAD concluded that the challenged claims are within its purview of review because they are not limited to representations that the products are “FDA approved” but also include comparative pain relief and “#1 Brand” claims. We also note that literally true claims regarding the Salonpas FDA approval, indication of pain relief, and duration of pain relief could be presented in a misleading fashion and those claims would certainly be within NAD’s purview of review, as they would be within ours.

Hisamitsu's ads have compared the efficacy of the Salonpas Pain Relief Patch and Arthritis Pain Patch to OTC drugs, such as medicated patches and oral pain relief medications.² The ads draw attention to the fact that the Salonpas Pain Relief Patch and Arthritis Pain Patch are unique among competing OTC pain relief drugs because they are FDA-approved and labeled to relieve a higher indication of pain, moderate pain (versus minor pain), for up to twelve hours. Hisamitsu's ads do not mention ThermaCare Heatwraps, a non-medicated device that provides pain relief through heat therapy, and we believe any comparisons implicit in these ads are with other medicated products.

Pfizer's argument that Hisamitsu is comparing itself to ThermaCare Heatwraps rests almost entirely on the close proximity of the two products on store shelves. We find Pfizer's argument unpersuasive in this instance. The materials Pfizer submitted show that the Salonpas pain relief patches are placed in just as close proximity, and in many instances closer proximity, to the competing medicated products actually referred to in Hisamitsu's advertising, than to the ThermaCare Heatwraps. We believe consumers viewing these products on the shelves will understand the significant differences between medicated patches that contain menthol and methyl salicylate versus a non-medicated, air-activated wrap that provides heat therapy.

Pfizer also contested Hisamitsu's FDA-approved claims, including the representation that "Salonpas is the first and only OTC pain patch clinically-proven and FDA-approved to relieve tough pain for up to 12 hours" because it believes that the FDA approval statement suggests that FDA has endorsed Salonpas versus competing products, including ThermaCare Heatwraps. We disagree. These and similar representations merely emphasize the fact that the Salonpas Pain Relief Patch and Arthritis Pain Patch are the only patches to receive FDA approval and that their effectiveness in temporarily relieving more intense aches and pains was clinically proven during FDA's review. We do not interpret this and similar representations to imply that FDA has endorsed Salonpas versus competing products.

Pfizer further questioned Hisamitsu's claims that Salonpas patches are the "#1 brand of patches in the world," the "largest brand of pain relief patches in the U.S.," and the "#1 pain patch worldwide and in the U.S.," maintaining that these statements convey the false message that Salonpas is "#1" because consumers believe it offers superior efficacy versus competing patches and wraps. We believe these claims simply convey the message that Salonpas patches are the bestselling patches, and not that consumers recognize Salonpas as a more effective pain reliever than competing products.

Finally, Pfizer challenged Hisamitsu's claim that the Salonpas Gel Patch Hot, which is unapproved, "soothes on contact" because it believes this claim implies immediate relief upon application of the patch to the site of pain. We note that on its website, Hisamitsu claims that the Salonpas Gel Patch Hot, "[s]tarts to cool on contact. Gel Patch Technology soothes the pain away and menthol cools on contact then delivers deep penetrating waves of heat. Capsaicin, the

² Hisamitsu's print and website advertisements compare these patches to Icy Hot Patch, Bengay Pain Relief Patch, Advil, and Tylenol Extra Strength.

Andrea C. Levine, Esq.

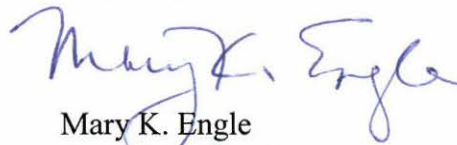
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actives in chili peppers, extends the pain relief for long lasting relief.” We believe the net impression of this ad is that the gel patch provides an immediate cooling sensation, not instantaneous pain relief. While other advertisements claim that the gel patch “soothes on contact,” we believe this phrase also denotes an instant cooling effect.

We regret that Hisamitsu chose not to participate in the NAD process because we fully support the self-regulatory process. However, for the foregoing reasons, the staff has determined not to take additional action at this time. We appreciate receiving your referral and having the opportunity to review this matter.

Very truly yours,



Mary K. Engle
Associate Director

cc: Daniel J. Manelli, Esq.
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