

Sheehan & Associates, P.C.
Spencer Sheehan
60 Cuttermill Rd Ste 409
Great Neck, NY 11021-3104
Telephone: (516) 268-7080
spencer@spencersheehan.com

United States District Court
Southern District of New York

1:20-cv-10272

Luz Sanchez, individually and on behalf of
all others similarly situated,

Plaintiff,

- against -

Avadim Health, Inc.,

Defendant

Class Action Complaint

Plaintiff by attorneys alleges upon information and belief, except for allegations pertaining to plaintiff, which are based on personal knowledge:

1. Avadim Health, Inc. (“defendant”) manufactures, distributes, markets, labels and sells Theraworx Muscle Cramp & Spasm Relief Foam (“Theraworx MCS” or “Product”), sold with a compression knee garment, with the active ingredient magnesium sulfate.

2. The Product is sold to consumers from retail and online stores, and directly by Defendant, in containers of various sizes.

3. The Product and its advertising contain numerous false, deceptive and misleading claims about its ability to provide pain relief.

4. These claims were recently the subject of a decision by the National Advertising Division (NAD) which concluded the claims and marketing were not accurate and misleading.

5. The Product is similar to external analgesic products which contain the active ingredients capsaicin, trolamine salicylate, and/or lidocaine.

6. The relevant FDA Monograph for these products limit the indications for use: “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.’).”

7. The Monograph states, “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.”

8. Defendant’s Product emphasizes its ability to provide pain relief of a more significant and enduring type than those covered by the Monograph, even though its active ingredient, magnesium sulfate, has not been reviewed or found to be generally recognized as safe or effective by the FDA to diagnose, treat, cure, prevent or mitigate any diseases or conditions.

9. The front label representations include “Muscle Cramp and Spasm Relief,” “Prevents Cramps & Spasms,” “Releases Muscle Tightness,” “Reduces Muscle Soreness” and “Foam with Magnesium Sulfate.”



10. Defendant's online marketing proclaims: "Apply as Needed for Fast Relief – As soon as you feel a muscle cramp or spasm coming on, use Theraworx Relief to quickly release muscle tightness and reduce the soreness afterwards. There's no limit to how many times you can apply it per day!"

APPLY AS NEEDED FOR FAST RELIEF

As soon as you feel a muscle
cramp or spasm coming on, use
Theraworx Relief to quickly release
muscle tightness and reduce the
soreness afterwards. There's no
limit to how many times you can
apply it per day!

11. Other online marketing describes the Product as “Fast-Acting Muscle Cramp Relief.”



12. The Product claims it “Prevents cramps and spasms, Releases muscle tightness, [and] Relieves muscle soreness.”



13. The representations on the packaging and website include:

- “REDUCES the severity of symptoms associated with RLS [restless leg syndrome].”
- “PREVENTS cramps and spasms when used daily.”
- “[Q]uickly relieves muscle cramps and even prevents them when used daily.”
- “Use Theraworx Relief twice daily (in the morning and before bedtime) to prevent nighttime muscle cramps and spasms, or three times daily if you also experience cramps or spasms during the day.”
- “Theraworx Relief for Muscle Cramps and Spasms can be used as a companion product to manage the leg cramps associated with many important, commonly prescribed medications.”

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.