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Clinical Trials Recommended For Pamprin Botanicals PMS Claims After Challenge By Bayer

Focus Consumer Appeals, Noting Bayer Challenged Clinical Trial Standard For Health Claims

by [Malcolm Spicer](#)

Focus Consumer Healthcare appeals NAD recommendation to pull or modify majority of express and implied claims on Pamprin Botanical product packaging, in advertising and Amazon listings challenged by Bayer Consumer.

The marketer of Pamprin Botanicals for premenstrual syndrome symptoms relief says its argument that clinical trials aren't the only acceptable substantiation for health claims is supported by a US court decision in litigation by the firm challenging its claims, [Bayer AG](#).

Focus Consumer Healthcare LLC is appealing a recommendation by the BBB National Programs Inc.'s National Advertising Division published on 22 January that it discontinue or modify the majority of the express and implied claims made on Pamprin Botanical product packaging and in advertising and Amazon product listings since the supplement's launch in 2023 and challenged by Bayer Consumer HealthCare.

The express claims included "clinically tested" and "scientifically tested"; among the implied claims, Pamprin Botanicals and Focus Consumer's Pamprin brand OTC drugs in multiple formulations combining acetaminophen with other active ingredients work together to provide superior relief for PMS symptoms (*see list below*).

As they have in numerous other reviews of health claims for supplements, NAD attorneys handling Bayer's challenge stated that clinical trials – in the form of randomized, placebo-

controlled clinical studies (RCTs) – are needed to support Focus Consumer’s claims for Pamprin Botanical.

The Chattanooga, TN-based firm, however, noted in its statement included in the NAD report that a federal court in 2015 ruled that the Federal Trade Commission inappropriately required Bayer to have RCT results to support claims that its Phillips Colon Health probiotic capsules help defend against occasional constipation, diarrhea, gas and bloating. (Also see "[FTC Stretched Standards In Enforcement Against Bayer Probiotic Claim](#)" - Pink Sheet, 5 Oct, 2015.)

Despite the ruling in US District Court for the New Jersey District and a similar ruling there in 2018 in other litigation challenging the FTC’s standard (Also see "[Another Court Ruling Rejects RCT Standard For Supplement Claims](#)" - HBW Insight, 30 May, 2017.), the agency has continued a policy of expecting health claims for supplement and other consumer health products to be supported by RCT results. (Also see "[FTC Leaves Supplement Industry Still Waiting For Shift Away From RCT Standard For Claims](#)" - HBW Insight, 6 Jul, 2016.)

And NAD attorneys referenced the FTC’s Health Products Compliance Guidance in their report. They wrote that the guidance “provides that ‘randomized, controlled human clinical trials ... are the most reliable form of evidence and are generally the type of substantiation that experts would require for health benefit claims’.”

As other supplement industry stakeholders have said about an RCT standard, Focus Consumer said in its statement that the NAD decision “is incorrectly based on a rigid substantiation standard applicable to prescription drugs.”

The New Jersey federal court agreed in Bayer’s challenge of the FTC standard that a clinical trial “is not and has never been the standard for dietary supplement claims,” Focus Consumer states.

“Decades of law and regulatory guidance support a finding that the breadth of studies on the individual ingredients in Pamprin Botanicals coupled with a well-designed clinical trial constitute competent and reliable scientific evidence in support of the supplement claims at issue.”

Focus Consumer will appeal the NAD attorneys’ findings to BBB National Programs’ National Advertising Review Board. The firm was launched in 2015 by former executives at [Sanofi’s](#) Chattem Inc. US business and marketed former Chattem brands Pamprin, Garlique supplements and Herpecin cold sore drugs; in October 2023, it was acquired by Japanese firm [Kobayashi Pharmaceutical Co. Ltd.](#)

‘Scientifically Tested’

Rings Of Trials

Bayer, which markets Midol OTC acetaminophen formulations for PMS syndrome relief, contended that some Focus Consumer express claims added up to an implied claim that Pamprin Botanicals was proven to reduce all common symptoms of PMS based on RCTs of the product.

The express claims include “clinically tested for safety and efficacy” on the Pamprin website and “clinically tested to help support your emotional and physical well-being before, during and after your period, which addresses underlying issues of PMS” in a post on Pamprin Botanical’s Instagram page, according to the report.

Bayer also objected to “scientifically tested” claims on Pamprin Botanical’s Amazon product page. One featured photos of Pamprin OTC products as well as Pamprin Botanicals and states “our products are scientifically tested, for efficacy on their own and safe to use in combination.”

Additionally, Bayer challenged the “mood support” claim on the front of product packaging as well as claims that taking two Pamprin Botanicals daily can “calm PMS symptoms,” “ease cramps, bloat and moodiness” and help consumers “experience a better period” as claimed in its Amazon product listing.

NAD attorneys determined Focus Consumer presented as evidence a trial which “suffered from several significant flaws which rendered the study insufficiently reliable to provide a reasonable basis for Pamprin Botanicals’ establishment and express health-related claims.”

According to the report, the trial allowed the participants to take OTC pain relievers during phase one of the study, which could have a material impact on survey results related to menstrual pain and bloating. It also relied upon survey results of subjective reactions of participants but lacked a control group as a basis for comparison.



LESS THAN A YEAR AFTER LAUNCH, PAMPRIN BOTANICALS' AD CLAIMS WERE CHALLENGED IN A NAD REIVEW. Source: Source: Shutterstock

Challenged Claims Reviewed

Express

- “clinically tested” and “scientifically

“There may be clinical studies that do not contain a placebo arm, like, for example, when there are ethical considerations around withholding treatment (i.e., life-saving treatments) or a placebo-arm is difficult or impossible to create, but none of those considerations are present in this case, nor did the advertiser show why a placebo was unnecessary,” NAD attorneys wrote.

While Focus Consumer noted the NAD in a previous review didn’t object to “general well-being claims” supported by non-blinded, non-placebo-controlled clinicals,” the attorneys said the firm “is not marketing Pamprin Botanicals product for general well-being but advertising that the product is clinically tested and can ease specific symptoms of PMS.”

NAD attorneys also rejected Focus Consumer’s argument that applying a placebo effect of 36% to 43% commonly found in PMS intervention trials to its study would still leave its the results better than the expected placebo rate. They agreed with Bayer that substituting a general placebo effect rate from other PMS intervention trials isn’t appropriate because Focus Consumer’s studies deviated in treatment mechanism, study population, response scale and definition of “response.”

As they have in numerous other consumer health product reviews, NAD attorneys concluded studies of the ingredients used in Pamprin Botanicals –ashwagandha, vitamin B6, chasteberry, magnesium and

tested”

- “Ashwagandha – a calming influence”
- “Magnesium – period pain, nope” and “works on period pain”
- “Vitamin B6 – pms less, chill more”
- “Turmeric – cramp pain & puff” and “helps cramps and puffiness”
- “Chasteberry – for a better period”
- “mood support”
- “calm PMS symptoms”
- “ease cramps, bloat and moodiness”
- “experience a better period”
- “scientifically tested, to holistically relieve the underlying causes of PMS symptoms”
- “Take 2 capsules daily”
- “2 days pre period to calm pms symptoms”
- “every day during your period to ease cramps, bloat and moodiness”
- “tried and trusted”

turmeric – weren't a good fit to support claims made for the product's formulation.

Split Decision On Claims Linking Supplement With OTCs

NAD attorneys agreed with Bayer on one point and with Focus Consumer on another concerning claims which link Pamprin Botanicals with the efficacy of the brand's OTC formulations.

Bayer argued that the Pamprin Botanicals description on Amazon states the brand's "medicinal products, like Pamprin Multi-Symptom, stand well alone but work so nicely in combination with the Pamprin Botanicals PMS, Period & Mood Support supplement to take good care of the whole you."

NAD attorneys that and similar claims suggest that the "supplement works together or in combination with Pamprin's OTC products to provide complete well-rounded care for the consumer." They noted "the disclaimer touting both products specifically states that it's safe to add either Pamprin OTC product 'to your period strategy for maximum relief'."

The "message reasonably conveyed ... is that Pamprin Botanicals and Pamprin OTCs work together to provide superior relief for PMS symptoms," a claim the attorneys recommended Focus Consumer modify its advertising to avoid making, the report states.

- Product is "botanical" and "naturally good for you"
- "all the good stuff, none of the bad"

Implied

- Competing products include ingredients that are unsafe or unhealthy.
- Pamprin Botanicals and Pamprin OTCs work together to provide superior relief for PMS symptoms.
- Pamprin Botanicals is all natural.
- The active ingredients are all natural.
- Implied claims that each ingredient in Pamprin Botanicals:
 - – Ashwagandha – reduces PMS-related mood swings
 - – Magnesium – reduces pain associated with PMS
 - – Vitamin B6 – reduces all PMS symptoms, including mood swings
 - – Turmeric – reduces PMS-related pain and bloating
 - – Chasteberry – reduces all PMS symptoms

The attorneys agreed with Focus Consumer, however, that the claim "tried and trusted" claim

refers to the brand's history and doesn't imply Pamprin Botanicals are comparable to the brand's OTC products.

The claim is part of advertising explaining that the brand launched in the 1960's, positioned itself as "period people" and has been revolutionizing period

symptoms ever since. All three Pamprin products are featured on the side of the advertisement.

- Pamprin Botanicals has been proven to reduce all common symptoms of PMS based on randomized, double-blind placebo-controlled testing of the product.

'Botanicals' Not Natural Claim

NAD attorneys also agreed with Focus Consumer that the brand Pamprin Botanicals isn't a claim that the product is all-natural.

"Nothing in the plain language of the name conveys the message that all ingredients in Pamprin Botanicals are plant based or that it is an all-natural product," the stated. Due to a lack of evidence of consumer confusion and their conclusion that "botanical" isn't an expressly false claim, they concluded the name Pamprin Botanical didn't require modification.

However, the attorneys recommended Focus Consumer discontinue or modify its use of "natural" in claims. One use reasonably conveyed a message that the listed ingredients alongside a leaf visual are natural.

"There is no evidence in the record as to whether the five ingredients listed are indeed natural," the attorneys explained, recommending Focus Consumer pull a "naturally good-for-you ingredients" claim and avoid conveying a message that Pamprin Botanicals' active ingredients are all-natural.

In a similar decision, they recommended the firm modify the claim "all of the good stuff, none of the bad" to avoid conveying a message that competing products include ingredients that are unsafe or unhealthy.

BBB National Programs appoints five-member NARB panels of advertising and marketing experts, including professors and executives, from outside the organization on a rotating basis to hear appeals of decisions by the organization's investigative units, the NAD and the Electronic Retailing Self-Regulation Program.