

EXHIBIT A

Case #4650 (04/02/07)

SIMILASAN CORPORATION USA

Earache Relief Ear Drops

Advertising Agency: *Undisclosed*

Challenger: *National Advertising Division*

- Health-related advertising claims must typically be supported by competent and reliable scientific evidence.

Basis of Inquiry: As part of its routine monitoring program, NAD requested substantiation for pharmacist recommended and performance claims made in a print advertising by Similasan Corporation USA for its Similasan Earache Relief Ear Drops. In the print advertisement, the product is shown beside a prominently featured claim, "#1 Ear Pain Reliever," next to which is the following text in larger print: "Recommended by Pharmacists 6 Times more often for Ear Pain over Tylenol, Motrin, and Aleve." The claims "Healthy Relief" and "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" also appear on the product packaging. The following claims are at issue:

"Recommended by Pharmacists six times more often for Ear Pain over Tylenol, Motrin, and Aleve combined."

"Healthy Relief."

"Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics."

Advertiser's Position:

- I. "Recommended by Pharmacists six times more often for Ear Pain over Tylenol, Motrin, and Aleve combined."

As support for this claim, the advertiser referred to a survey conducted by Pharmacy Times magazine of brands most recommended by pharmacists for earache relief which revealed that Similasan received 49.43 percent of the recommendations as compared to Tylenol, Motrin, and Aleve (receiving a combined 7.9 percent of the recommendations). During the pendency of the inquiry, the advertiser informed NAD that it would permanently discontinue the "Recommended by Pharmacists six times more often for Ear Pain over Tylenol, Motrin, and Aleve combined" claim because a review of the study's methodology revealed that only two products were named for earache relief (though some write-ins listed other products).

- II. "Healthy Relief"; "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics."

The advertiser asserted that the claim "Healthy Relief" is a tagline and a registered trademark for its line of homeopathic drug products and is referenced in the advertisement solely because it appears on the product packaging. However, the advertiser noted that its product packaging and advertising prominently disclose that the product is homeopathic in nature and maintained that homeopathic manufacturers are not required to prove the safety and efficacy of their products.

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The advertiser explained that "Healthy Relief" is intended to convey to consumers that the company's homeopathic products are different than typical over-the-counter (OTC) drugs because they are intended to treat symptoms without the use of chemicals that can cause side effects and interactions with other drugs. The advertiser noted that the level of active ingredients in homeopathic products is approximately 10 percent and that the product is further diluted. The advertiser argued that its product is marketed and labeled in compliance with the U.S. Food and Drug Administration's (FDA) compliance policy guide, "Conditions Under Which Homeopathic Drugs May be Marketed" (CPG)¹, in that it complies with both the requirements of the Homeopathic Pharmacopoeia of the United States (HPUS)² and that the concentrations of each of its ingredients is far below the maximum level allowed by the HPUS for OTC products as the most concentrated ingredient is present at one part per trillion.

The advertiser also maintained that the term "Healthy Relief" was based on the results of a survey³ it conducted to determine consumers' takeaway of the term. Consumers who visited the Similasan Website were asked "What does Healthy Relief mean to you?" and of the 5,320 respondents, 70 percent associated the phrase "Healthy Relief" with the following attributes: no known side effects (16 percent), pain relief (16 percent), contains no harsh chemicals (14 percent), treats symptoms (13 percent), and safe to use (11 percent).

As to the claim, "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" the advertiser argued that its product has not been shown to cause side effects or interact with other drugs and that there are no confirmed cases where homeopathic drugs were determined to be the cause of an illness or side effect. It noted that the FDA found that in the few reported cases of illness associated with the use of homeopathic remedies, the remedies were not likely to be the cause because the active ingredients were highly diluted. The advertiser averred that while no study has been conducted on a product which contained the exact formulation as the Similasan product, and that such is not in any case necessary, it referred to two clinical trials using products that contain the active ingredients in the Similasan product. Taken together, the advertiser argued that the claim that Similasan "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" was substantiated.

Decision:

During the pendency of this inquiry, the advertiser informed NAD in writing that it had permanently discontinued the claim "Recommended by Pharmacists six times more often for Ear

¹ FDA/ORA CPG 7132.15, *Conditions Under Which Homeopathic Drugs May Be Marketed*. Adopted by the FDA in 1988, the CPG offers guidance to industry in the marketing of homeopathic drugs.

² The HPUS defines the legal standards for strength, quality and purity for drug products in order for them to be officially labeled as homeopathic drug products and is referenced as the legal source of information on homeopathic drug products in the Federal Food Drug and Cosmetic Act (21 U.S.C. § 301). It is administered and updated by the Homeopathic Pharmacopoeia Convention of the United States.

³ The advertiser advised that consumers can access the Similasan website through a variety of search engines and that they are referred to the survey upon clicking on a link called "valuable coupon" which they need to complete before they can download the coupon. The advertiser noted that its website makes clear that the survey is optional.

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Pain over Tylenol, Motrin, and Aleve combined," an action NAD deemed necessary and appropriate given the flaws in the underlying study.

As to the "Healthy Relief" claim, NAD determined that its placement on the product packaging (directly under the brand name and not in conjunction with the performance claims) is likely to be understood by consumers to be a designation for the advertiser's line of homeopathic products rather than a product performance claim requiring substantiation.

Concerning the claim that Similasan "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics," there are two distinct components: the efficacy claim (relieves pain, soothes and calms) and the safety claim (safe for use with antibiotics). As to the efficacy claim, NAD determined that the underlying issue is not whether the ingredients in the product meet the legal standards for strength, quality and purity for drug products as defined by the HPUS or the CPG but, rather, whether there is sufficient evidence that the product itself actually soothes, calms and relieves ear pain.

It is well-established that claims concerning the efficacy of health products should be supported by competent and reliable scientific evidence.⁴ In cases that involve express claims of product performance, an advertiser should affirmatively demonstrate that the advertised product actively performs the function or provides the benefit claimed in the advertisement.⁵ However, NAD recognizes that there may be instances when general product efficacy claims promising health benefits can be substantiated without clinical studies of the specific product in question (e.g., the efficacy of certain ingredients for the claimed benefit) where the advertiser demonstrates that it is scientifically sound to draw conclusions from reliable studies and data and apply them to the performance claimed by the advertised product.⁶

As support for the "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" claim, the advertiser submitted two clinical studies on ingredients in the advertiser's product as well as excerpts from homeopathic texts.

As to the clinical studies, neither used a treatment whose formulation is similar to that found in the Similasan product; rather, both used single ingredient treatments. The first study involved a six-week randomized, double-blind placebo controlled pilot study of 75 children aged 18 months to six years of age diagnosed with acute otitis media (AOM).⁷ The infants assigned to the

⁴ Matrixx Initiatives, Inc./Zicam L.L.C. (Zicam Cold Remedy Nasal Gel), Report # 4286, *NAD Case Reports* (February 2005); Green Pharmaceuticals, Inc. (SnoreStop), Report # 4013, *NAD Case Reports* (January 2003).

⁵ Playtex Products, Inc. (Baby Magic Bath Products and Baby Magic Shampoo), Report # 3680, *NAD Case Reports* (August 2000).

⁶ Council on Natural Health (Smoke Away System), Report # 4180, *NAD Case Reports* (May 2004) (where NAD determined that the advertiser of a homeopathic product provided reliable scientific evidence as to the ingredients in its product being helpful in assisting smokers in their attempts to quit smoking though it did not support the claims that it will make them smoke-free or eliminate cravings or withdrawal symptoms).

⁷ Acute otitis media is the presence of fluid, typically pus, in the middle ear with symptoms of pain, redness of the eardrum, and possible fever. In this study, 36 children received a homeopathic treatment and 39 were given a placebo. Of the 16 different homeopathic medicines that were available (and most commonly used to treat AOM),

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homeopathic group received one of eight possible treatments including chamomilla and sulphur both of which are present in the Similasan product. Indeed, the authors of the study stated that the purpose of the study was to determine which homeopathic treatment(s) (which consisted of one ingredient) would be appropriate to treat AOM. At the outset, the authors noted that AOM in children heals spontaneously without therapy in most cases. 'The infants' parents were asked to record a diary of symptoms which included pain, fever, irritability, appetite, energy and sleep and tympanograms (a test used to detect disorders of the middle ear) were taken of the subjects to determine the amount of middle ear effusion at the beginning of the study and at weeks two and six. The authors concluded that there was a decreased symptom score at all points during in the study for the group receiving homeopathic medicine as compared to placebo, with a significant decrease in symptoms at 24 and 64 hours after treatment, and no reported side effects, which it deemed noteworthy though it noted that a larger study would be needed to verify the results. They also referred to a metaanalysis of 89 homeopathic trials which found, at a 95 percent confidence level, insufficient evidence that homeopathy is clearly efficacious for any single clinical condition.

The second study was an open nonrandomized non-blinded, observational study of 131 children, with 103 children receiving one of 12 possible homeopathic treatments (consisting of one ingredient) and 28 receiving a conventional treatment (nasal drops, antibiotics, secretolytics and/or antipyretics). The main outcome measures were duration of pain, duration of fever and the number of recurrences after one year. As in the first study, the children in the homeopathic group were assessed individually by a qualified homeopathic practitioner and prescribed the most appropriate remedy according to their specific presentation of symptoms. The study concluded that homeopathy may provide a good alternative to conventional treatment in that reduced symptoms were reported in the homeopathic group compared with those in the conventional treatment group (including decreased duration of pain and fewer recurrences after one year), with no serious side effects reported from either group (with only slight side effects in the conventional treatment group). The authors acknowledged, however, that the study was unreliable because it was not randomized or double-blind.

While the studies' authors noted the importance of individualization of homeopathic treatment, whereby patients with the same medical diagnosis might receive different medicines based on specific symptoms of illness in each patient, NAD is not charged with determining which course of treatment is preferable but instead looks to the claim at issue to determine if the scientific evidence constitutes reliable support. Serious methodological flaws and the preliminary nature of the findings on the efficacy of homeopathy in treating AOM undermine the reliability of both studies. Importantly, both of these studies were designed to measure the effectiveness of a homeopathic treatment (consisting of only one ingredient) compared with conventional medicine or placebo and not a combination of ingredients as present in the advertiser's product. In

eight were prescribed by the homeopathic practitioners. The most common medicines prescribed in 88 percent of the cases were Pulsatilla nigrans (62.7 percent), Chamomilla (10.7 percent), Sulphur (9.3 percent) and Calcarea carbonica (5.3 percent). Each child was seen by homeopathic practitioners (two medical doctors and a physician's assistant) and a naturopathic physician. Follow-up visits were made by an otolaryngology resident.

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addition, it is unclear which of the homeopathic ingredients (particularly Chamomilla, Mercurius solubilis and Sulphur found in the Similasan product) was deemed effective in helping to relieve AOM symptoms to even afford the possibility of an ingredient claim.⁸ Further, the dilutions of the ingredients in the studies differ from those in the advertiser's product. As such, the studies are insufficiently reliable to afford extrapolation of their findings to support the efficacy portion of the challenged claim ("Relieves Pain, Soothes & Calms").

NAD also reviewed excerpts from homeopathic literature⁹ on the ingredients in Similasan and determined that while these sources may support the legal standards for strength, quality and purity for drug products as prescribed by HPUS or the CPG and reveal the potential efficacy of the individual ingredients in relieving symptoms associated with AOM, there is no evidence in the record which demonstrates that the efficacy of individual ingredients will not be diminished in any way with the addition of other ingredients, since Similasan contains a *combination* of ingredients, particularly given that they are even more diluted than required by the HPUS.¹⁰

As to the "Safe to Use With Antibiotics" portion of the claim, NAD determined that the fact that the ingredients in the product are highly diluted cannot in and of itself provide sufficient support for a claim that the product is safe to use with antibiotics. As NAD has noted in past decisions, it is very important that claims relating to the safety of health-related products be supported by competent and reliable scientific evidence.¹¹ This is particularly important with respect to homeopathic drugs, since marketers of homeopathic drugs are not required to prove their safety before they are sold to the public, and is supported by the CPG which specifically provides that a product's compliance with requirements of the HPUS does not establish that it has been shown "by appropriate means to be safe, effective and not misbranded for its intended use."¹²

For all the foregoing reasons, NAD recommended that the claim "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" be discontinued.

Conclusion:

NAD appreciated that the advertiser voluntarily discontinued its claim, "Recommended by Pharmacists six times more often for Ear Pain over Tylenol, Motrin, and Aleve combined," an action it deemed to be necessary and proper given the evidence in the record. NAD determined that the advertiser's evidence was not sufficiently reliable to support the claim "Relieves Pain, Soothes & Calms, Safe for Use With Antibiotics" and, accordingly, recommended its discontinuance.

⁸ See, e.g., Avon Products, Inc. (CELLU-SCULPT Anti-Cellulite Slimming Treatment), Report # 4124, *NAD Case Reports* (December 2003).

⁹ John Henry Clarke, M.D., *A DICTIONARY OF PRACTICAL MATERIA MEDICA* (Health Science Press); Douglas M. Gibson, *STUDIES OF HOMEOPATHIC REMEDIES* (Beaconsfield Publishers Ltd.).

¹⁰ Playtex Products, Inc. (Baby Magic Bath Products and Baby Magic Shampoo), Report # 3680, *NAD Case Reports* (August 2000).

¹¹ Patent HEALTH, LLC (Fluid Joint - Dietary Supplement for Joint Function), Report # 4335, *NAD Case Reports* (May 2005).

¹² *Supra* note 1.

Advertiser's Statement:

Similasan Corporation USA welcomes the opportunity to participate in this process and appreciates the important role that the NAD plays in industry's self-regulatory scheme. In this case, however, Similasan regretfully concludes that the NAD has reached an incorrect result as to the core claims it has challenged. Similasan appreciates that the NAD agrees with its position that "Healthy Relief" is not a performance claim but rather a designation for Similasan's line of homeopathic products. The performance "claims" which are the subject of this inquiry appear on a photo of Similasan's Earache Relief Drops package in a free standing circular. The claims appear on the principal display panel of the package and on the Drug Facts panel. Similasan believes, and the NAD does not dispute, that this product is labeled and marketed in accordance with the Food and Drug Administration's Compliance Policy Guide (CPG) on the sale of homeopathic drugs, a special category of drugs specifically recognized in the Federal Food, Drug, and Cosmetic Act since its passage in 1938. Yet the NAD believes that showing a photo of a legally marketed product is indefensible because the product does not have "scientific" evidence to support those claims in the manner that the NAD believes is required. Similasan does not agree that legally appropriate claims on a product package are somehow inappropriate when they appear in advertising.

Homeopathy is an alternative school of medicine which has existed for more than 200 years. It does not rely upon nor especially embrace the value of clinical trials to demonstrate efficacy. As a result, very few homeopathic drugs have undergone clinical testing. FDA fully understood that this was the case when it issued its Compliance Policy Guide in 1988 concerning the marketing of homeopathic drugs. The NAD appears to be imposing a standard of proof which is imposed neither by the FDA nor the Federal Trade Commission. Under the NAD's view, virtually no homeopathic drug could be advertised to the public. That is surely an incorrect result.

It is the homeopathic literature (the materia medica), not clinical trials, which are the foundation for claims of homeopathic efficacy, and these references are recognized as such by FDA's Compliance Policy Guide. The NAD's assertion that a homeopathic product must prove that "the efficacy of individual ingredients [in a combination product] will not be diminished in any way with the addition of other ingredients" is misplaced. Neither the HPUS nor the FDA require such "proof." Similasan does not accept the NAD's view that a legally marketed homeopathic drug may not be advertised to the public.

Nonetheless, because of its respect for the NAD and the self-regulatory process, Similasan will take the NAD's recommendations into account when developing future advertising and will not use again the advertisement in question. (#4650 AMU/AT, closed 04/02/2007)