Claims: Health and Wellness at NAD

Advertising claims that promise to treat or reduce the risk of developing a disease or condition are considered "health claims" and , on labeling, are regulated by the U.S. Food and Drug Administration (FDA). In marketing and advertising, "health" claims, as with other advertising claims are also the province of the Federal Trade Commission (FTC) and the subject of the self-regulatory program of the National Advertising Division (NAD) of the Better Business Bureau National Partner Program (BBBNP).

Health claims (and "health lite" claims) have been the subject of frequent NAD decisions and have been the subject of NAD's monitoring programs. In rendering guidance and issuing decisions and recommendations, NAD looks to FTC law and guidance, including the Commission's 2022 Health Products Compliance Guidance. NAD, like the FTC, has determined that health claims, and "health-related" claims, should be supported by "competent and reliable scientific evidence" which is defined as:

> "tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; and (2) are generally accepted in the profession to yield accurate and reliable results." In addition, the FTC requires that the research must be "sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true."

The following are representative of NAD's recent findings and decisions in its review of claims (express and implied) relating to health and wellness:

I. *Gruma Corporation (Tortillas),* Report #7333, NAD/CARU Case Reports (August 2024)

In a challenge brought by Olé Mexical Foods, NAD evaluated whether Gruma's Mission Zero Net Carb Tortilla Original and Sundried Tomato Basil products and Guerrero Zero Net CarbTortillas Original – High Fiber and Chipotle - High Fiber products use a serving size that is inconsistent with Food and Drug Administration (FDA) regulations and industry practice.

Based on FDA regulations, a serving size for the challenged product is three tortillas. Competitors' label claims are based on this FDA standard serving size. Gruma based its zero net carb and other fat and sugar labeling claims on a smaller 18g, or one tortilla serving size. NAD found that consumers cannot evaluate or accurately compare the label claims on competitive products if the serving sizes among a product category are inconsistent. Therefore, NAD determined that the zero net carbs, zero sugar, and 1.5g fat claims based on a one tortilla serving size are misleading in a marketplace with FDA regulations specifying "per serving" calculations.

Gruma argued that its testing supports a "zero net carbs" and "zero sugar" claim even on the FDA compliant 54-gram serving size; therefore NAD also considered the accuracy of nutrition claims regarding net carbohydrates and sugars for the 54-gram serving size. NAD found the "zero net carb" claim was supported and recommended that Gruma modify its net carb calculation to use total carbohydrates minus dietary fiber for the 54-gram serving size. NAD also found the "zero sugar" and "0G sugar" claims on the 54-gram serving size of the Mission and Guerrero Zero Net Carb Original and Guerrero Zero Net Carb Chipotle tortilla products were supported but recommended these claims be discontinued for the Mission Zero Net Carb Sundried Tomato Basil Tortilla.

NAD also noted that the 1.5-gram total fat claim would increase with the serving size of 54 grams. Therefore, NAD did not consider the evidence to support the total fat claim and recommended that Gruma discontinue "1.5G Total Fat Per Serving" for all of the challenged products.

II. *Happy Mammoth (Hormone Harmony),* Report #7236, NAD/CARU Case Reports (August 2024)

As part of its monitoring program, NAD reviewed health related claims by Happy Mammoth for its Hormone Harmony dietary supplement including:

- *"Relieves symptoms of Menopause"*
- *"Relieves hot flashes"*
- *"Improve sleep quality"*
- *"Reduces bloating and gas"*

The product at issue, Hormone Harmony contains a proprietary combination of ingredients, including fennel, chaste berry, ashwagandha, and chamomile, to ease menopausal discomfort.

NAD determined that Happy Mammoth did not have a reasonable basis for the unqualified claims about the challenged benefits as there was notesting on the product itself. However, Happy Mammoth indicated a willingness to qualifythe challenged claims to specify the efficacy of the ingredients in delivering the challenged benefits. Therefore, NAD examined whether the evidence could support qualified claims.

NAD determined that the studies submitted by Happy Mammoth had limitations that rendered them insufficient to support the challenged claims as well as the qualified claims and, therefore, recommended the claims be discontinued. NAD noted that nothing in its decision would prevent Happy Mammoth from making claims regarding the ability of fennel and chaste berry to positively affect menopausal symptoms that are supported by the limited findings of the research in evidence, or claims that describe the traditional or historic use of ashwagandha to support sleep or are carefully qualified to avoid any misleading implication about the product's efficacy or health benefits.

III. *ASO LLC (Hydrocolloid Gel Bandages)*, Report #7325, NAD/CARU Case Reports (August 2024)

Johnson & Johnson challenged claims by ASO LLC including the claim, "2x faster healing" for its hydrocolloid bandages. Hydrocolloid bandages are moist wound dressings that turn into a gel after absorbing fluid. ASO's bandages are sold under their brand names, All-Health and Care Science. The claim, "up to 2x faster healing" claims appeared on several media platforms, on the bandage packaging, and retailer websites. The claim appeared adjacent to ASO's "SMART-

HEAL®"trademark with the disclosure "*Hydrocolloids have been shown to heal minor cuts, scrapes, abrasions, lacerations, blisters, and scalds up to 2x faster than a simple dry bandage. Journal of Athletic Training 2007; 42(3):422-424.")

NAD concluded that some consumers looking at ASO's advertising might take away the message that the "up to 2x faster healing" claim is a comparison between hydrocolloid bandages and traditional dry bandages.

NAD determined that the advertising also conveyed that ASO's product, or its Smart-Heal Technology, as opposed to hydrocolloids generally, promotes up to 2x faster healing.

NAD found that while ASO's evidence suggests hydrocolloids may speed the wound healing process, it does not reasonably support qualified claims that hydrocolloids have been shown to heal up to 2x faster than dry bandages. As a result, and because ASO provided no evidence of its own bandages' relative healing times, NAD determined that the evidence also does not support claims that ASO's product or its Smart-Heal Technology promotes up to 2x faster healing.

NAD recommended that ASO discontinue its "up to 2x faster healing" claims.

In addition, Johnson & Johnson argued that ASO's "up to 2x faster" claims falsely imply that ASO's hydrocolloid bandages have premarket approval from the FDA as Class III medical devices. NAD did not find that any of the challenged advertising or claims reasonably conveyed such a message.