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MEMORANDUM

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Re: **National Advertising Division Issues Decision on "100% Natural," Satiety, and Curbing Cravings Claims**

A recent action by the National Advertising Division (NAD), a self-regulatory arm of the Better Business Bureau, addresses the level of proof necessary to support "natural" and "satiety" claims involving competing experts and a variety of scientific data in dispute. 1/ The Proctor & Gamble Company (P&G) successfully challenged three claims made by GlaxoSmithKline Consumer Healthcare, LLC (GSK) for its Benefiber Original and Benefiber Healthy Shape products. GSK disagreed with the case outcome, appealing NAD's findings and recommendations to the National Advertising Review Board (NARB). Beyond the NAD's specific findings, the decision also provides useful insight into how NAD evaluates health benefit and related claims and analyzes the corresponding scientific evidence and other substantiation. The outcome of the NARB appeal will likely shed further light on how the claims substantiation issues involved should be addressed by advertisers in the future.

Background

For the referenced products, the challenge focused on three claims: "100% natural," "clinically proven to curb cravings," and "helps you feel fuller longer." GSK provided substantiation for all three claims. The NAD, however, did not accept GSK's substantiation as a good fit for the claims in question and recommended that all three claims be discontinued. The Decision includes an assessment of the relevant science and the fit between the scientific evidence and the consumer benefit claimed. This memorandum focuses on NAD's findings. Please see the Decision for a complete summary of the parties' positions.

1/ GlaxoSmithKline Consumer Healthcare, LLC / Benefiber Original and Benefiber Healthy Shape, NAD Case # 6366 (May 14, 2020). *See also*, Press Release, "NAD Recommends GlaxoSmithKline Discontinue Benefiber Claims of "100% Natural," Satiety, and Curbing Cravings; Advertiser to Appeal" (May 26, 2020), https://bit.ly/3dh7Nnv.

100% Natural Claim

Benefiber contains a single ingredient, wheat dextrin, a non-digestible ingredient with 85% fiber content that is derived from wheat starch, a digestible ingredient with 0% dietary fiber. The ingredient is the subject of a Generally Recognized as Safe (GRAS) Notification to the U.S. Food and Drug Administration (FDA) and its manufacturing process is patented. P&G challenged the 100% natural claim on the basis that Benefiber "is extensively processed in a manner than involves significant chemical and structural transformations to yield a compound not found in nature" and therefore should not be considered "100% natural." GSK argued its "100% natural" claim was not misleading for several reasons: the manufacturing process is "incredibly basic;" wheat dextrin can be found in nature; wheat dextrin is a natural product under FDA and Federal Trade Commission (FTC) precedent; and the changes that take place in production are structural and not compositional in nature, meaning the process does not create a new molecule.

NAD recommended GSK discontinue the "100% natural" claim because "the processing of wheat starch to yield the wheat dextrin found in Benefiber represents a significant alteration of the source ingredient that is inconsistent with a consumers' reasonable understanding of a product that claims to be 100% natural."

NAD took issue with both the "100%" and "natural" aspects of the claim. NAD noted that quantified claims have a strong impact on consumers and that a "100%" claim "conveys a message of completeness and certainty," such that a "100% natural" claim communicates a "promise[] to deliver a substance that is entirely natural" and that only minimal processing, if any, is required to bring the product to market. In rejecting GSK's argument that the processing methods are "incredibly basic," NAD cited to the company's patent and GRAS Notification as support that the various processing steps do not accord with consumers' expectation of a product that is "100% natural." NAD found the production process for Benefiber includes multiple steps, uses hydrochloric acid, added enzymes, and a "tailored, highly controlled method," which is inconsistent with consumers' expectations of a "100% natural" product.

Turning to use of the "natural" claim standing alone, NAD dismissed GSK's position that wheat dextrin is natural because it is found in nature, specifically in wheat seedlings, when the human body digests starches, and when wheat starch is cooked (i.e., in bread). NAD reasoned that those naturally occurring instances are not the source of the wheat dextrin used in Benefiber and citing to them "largely ignores the specific processing required to transform the wheat starch source ingredient into the wheat dextrin found in Benefiber." Additionally, NAD noted that in FDA's *Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates* the agency identified wheat dextrin as a "synthetic" non-digestible carbohydrate. NAD also stated in a footnote that while FDA has not defined natural, the agency's informal guidance "was not intended to address food production methods."

Finally, NAD rejected GSK's argument that the manufacturing process does not create a new molecule, and therefore should be considered "natural." NAD concluded that "even if the source and final ingredients have the same molecular formula" consumers' expectations for a "100% natural" claim more likely are focused on the extent of processing and transformation.

Cravings and Satiety Claims

NAD determined that the Benefiber advertising included an establishment claim – "clinically proven to curb cravings" – and a health-related satiety claim – "helps you feel fuller longer" – both of which must be supported by reliable, competent scientific evidence. According to NAD, that typically means "human clinical trials that are methodologically sound and statistically significant." Importantly, the Decision also emphasized that the evidence must show effectiveness in the relevant population. In the case of Benefiber, NAD determined that GSK must demonstrate that the daily dose of 14.8 grams of fiber "curbs cravings" in U.S. customers, and helps them "feel fuller longer." NAD reviewed seven studies submitted by GSK but found none supported the advertiser's claims, for reasons including:

- **Non-US Population.** Several of the submitted studies were conducted on non-U.S. populations with different or unknown dietary fiber intake in conditions that were not relevant to U.S. consumers and/or whose health status was not representative of the target population. 2/

- **Different substance tested.** One of the submitted studies tested soluble corn fiber, a distinctly different ingredient that could not be considered functionally equivalent to wheat dextrin, according to NAD.

- **Biomarkers distinct from human perception claims.** Two studies measured biomarkers of satiety; however, NAD reasoned that cravings and fullness claims are tied to human perception, so the use of biomarkers alone is not sufficient to support the claim.

- **Incomplete study.** One study was submitted in abstract form only. Because NAD was not provided access to the full study, it was unable to assess its reliability.

In its Advertiser's Statement, GSK stated it "firmly believes that the challenged claims are supported" based on the science relied upon and NAD precedent, and will appeal to the NARB. 3/

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We plan to provide an update once an NARB Decision is issued in this dispute. Should you have any questions, please contact us.

2/ According to the Decision, both FTC and FDA guidance regarding substantiation for dietary supplement products recommend that supporting studies should have a population that reflects the characteristics and lifestyle of the population targeted by the advertisement.

3/ The NARB is the NAD's appellate body, comprised of industry professionals, providing a five-person industry peer review of NAD decisions, when appealed. Each appeals panel consists of three national advertisers, one agency representative, and one public sector representative.