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WHITE PAPER

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Consumer Product Food Labeling: Reaching a "Healthy" Balance

Earlier in 2021, the FDA issued a notice that it will be conducting preliminary consumer research on the use of a voluntary symbol that could be used to depict the nutrient content claim "healthy" on packaged foods. Congress has also introduced the Food Labeling Modernization Act of 2021 that would, among several things, require front-of-pack labels to include health-oriented symbols related to the nutrients in the food. All this comes at a time when consumers' demand for healthy food is driving manufacturers and other industry participants to innovate and share their brand developments. However, given the regulatory landscape (and a plaintiffs' bar ready to leverage any change in the law to attempt to open new fronts of often unfounded claims) associated with health claims, food companies are understandably wary of making claims about the health benefits or nutritional content of their products.

This *White Paper* discusses how industry participants can strive to reach a "healthy balance" when labeling their products, so as to provide consumers the information they seek and to promote the food's qualities and benefits, while mitigating potential litigation and regulatory risks.

Consumers are increasingly interested in food that is both tasty and healthy. This demand for healthy food is driving manufacturers and other industry participants to innovate and share their brand developments, including the nutritional information consumers seek to make healthy choices. However, given the regulatory landscape (and a plaintiffs' bar ready to leverage any change in the law to attempt to open new fronts of often unfounded claims) associated with health claims, food companies are understandably wary of making claims about the health benefits or nutritional content of their products. As detailed below, industry participants should strive to reach a "healthy balance" when labeling their products, so as to provide consumers the information they seek and promote the food's qualities and benefits, while mitigating potential litigation and regulatory risks.

BACKGROUND

Consumer product manufacturers are no strangers to consumer class actions. These lawsuits target a wide range of products, claiming (often without basis) violations of state consumer fraud and false-advertising statutes, common-law fraud, and breaches of express and implied warranties for allegedly false, misleading, or deceptive label or packaging claims. The food and beverage industry has endured a surge of these cases, particularly in the last decade. As an example, the food industry has been the target of numerous class-action lawsuits related to "all-natural" claims.[1]

Most recently, plaintiffs have focused on supposed express or implied health claims on the labels and packaging of food products. In these cases, consumers claim that they were misled to believe the food product was "healthy" or "healthier," only to discover after their purchase that the food had no added health benefits or, in some cases, was actually detrimental to consumer health. These claims include theories that including certain ingredients, such as sugar or certain fats, or the function of an ingredient, such as citric acid as a preservative, detrimentally affect a person's health.[2]

At the same time as consumers have increased their attention on alleged health claims, so too have regulatory agencies. The Food and Drug Administration ("FDA") has increased its focus on continuing to ensure that product labeling provides accurate and nonmisleading nutrition information to consumers. This initiative is part of FDA's Nutrition Innovation Strategy, which serves to "empower consumers with information and facilitate industry innovation toward healthier foods that consumers want."[3] Companies that fail to comply with FDA labeling regulations may face, in addition to potential class action suits, FDA regulatory enforcement. When FDA issues a warning letter or engages in other enforcement activity, whether or not that action is warranted, consumers and the consumer class action plaintiffs' bar pay attention, filing add-on litigation claims, claiming they were misled by allegedly noncompliant labels.

Congress also is paying attention to food labeling and nutrient content claims. On August 3, 2021, Congress introduced the Food Labeling Modernization Act of 2021, which would amend the Food, Drug, and Cosmetic Act and change requirements regarding the nutrient information found on food labels.[4] Among the proposed changes, the legislation would require the front-of-pack labels to include health-oriented symbols related to the nutrients contained in the food. The legislation would also require manufacturers and importers of foods to submit to FDA all labeling information, including the image of the principal display panel, nutrient-content claims, and health-related claims, a major shift in food labeling policy. Failure to submit such information, or update or supplement it, could result in civil penalties.

Notwithstanding an eager plaintiffs' bar and an increasingly active FDA, food manufacturers can continue to serve their consumers by sharing their product innovations. The key is to maintain a healthy balance between sharing information and understanding and mitigating potential legal and regulatory risks.

FDA POLICY AND RULES REGARDING "HEALTHY" AND NUTRIENT CONTENT CLAIMS

FDA announced its Nutrition Innovation Strategy ("NIS") on March 29, 2018, as part of its efforts to "reduce preventable death and disease related to poor nutrition."[5] Through the NIS, FDA aims to advance its public health mission by empowering consumers "to make better and more informed decisions about their diets and health," as well as foster innovation and the development of healthier food options.[6] The NIS is focused on six key elements: (1) modernize health claims; (2) modernize

standards of identity; (3) modernize ingredient information to make it more consumer friendly; (4) implement the nutrition facts label and menu labeling; (5) reduce sodium in food supply; and (6) improve nutrition education.[7]

As part of the modernizing health claims component, FDA aims to revise permissible claims in a way that provides "quick signals" to consumers of a food's potential health benefit. At the same time, FDA wants to incentivize marketplace competition by encouraging participants to "reformulate products" in order to improve the product's "healthy qualities."[8] One claim FDA intends to update is the authorized use of the term "healthy"—an implied nutrient content claim. This too has been proposed by Congress through the recently introduced Food Labeling Modernization Act.

Background on "Healthy" Claims

Nutrient content claims characterize the level of a nutrient in a food. These claims can be express or implied. Implied nutrient content claims "imply that a food, because of its nutrient content, may be useful in achieving a total diet that conforms to current dietary recommendations."[9] A claim that the level of nutrients a food contains contributes to good health is by definition an implied nutrient content claim and directly falls within the purview of FDA's regulatory authority. The Food, Drug, and Cosmetics Act ("FD&C Act") allows for the use of such labeling claims, as long as these labels and claims are made in accordance with FDA regulations.[10] One such claim is use of the term "healthy."

In the 1990s, FDA found that the purpose of a "healthy" claim is to highlight those foods with nutrient levels useful to constructing a diet that conforms with dietary guidelines.[11] At the time, the country was focused on reducing fat in consumers' diet.[12] Thus, when defining the term "healthy," FDA promulgated a rule that permits the use of a "healthy" implied nutrient content claim for foods that allow a consumer to meet certain prescribed conditions for total fat, cholesterol, and other nutrients.[13] The rule did not address sugar content or distinguish between good and bad types of fat (e.g., mono- and polyunsaturated vs. trans fats). This meant that based on fat content, strictly speaking, foods relatively high in total fat like avocados or nuts may not be considered "healthy," while foods like sugary cereals and pudding could be labeled as "healthy."

In March 2015, FDA sent a warning letter to KIND, stating that certain of its labels could not contain the term "healthy" because the nut content of the bars resulted in a total fat content that exceeded FDA's definition of "healthy." This spawned a flurry of consumer lawsuits against KIND for violation of consumer protection laws.[14] KIND filed a citizen's petition with FDA, requesting it revisit its "outdated" definition of the term "healthy." FDA responded by stating that KIND could continue to use "healthy" in its label, but "only in text clearly presented as its corporate philosophy," not as a nutrient content claim.[15] FDA also agreed that its "healthy" definition was "due for a reevaluation in light of evolving nutrition research."[16]

In September 2016, FDA published "nonbinding recommendations" for the use of the term "healthy" and stated that it would exercise enforcement discretion during the rulemaking process if the food met the requirements under the current regulation, or if the foods: "(1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D."[17]

FDA Consumer Research

On May 7, 2021, FDA issued a notice that it will be conducting preliminary consumer research on the use of a voluntary symbol that could be used to depict the nutrient content claim "healthy" on packaged foods.[18] This procedural notice seeks comment on "ways to enhance the quality, usefulness and clarity of the information to be collected."[19] Draft "healthy" symbols were included as part of the Supporting & Related Material to the notice.[20] FDA also intends to publish a proposed rule to update the definition of the "healthy" content claim.

The comment period for the procedural notice closed on July 6, 2021, with 42 public comments submitted. Several interested parties supported FDA's proposed "healthy" label and applauded FDA's overall NIS initiative. Many expressed the importance of revisiting and revising the "outdated" definition of "healthy" in order to have a "clear and consistent definition" in the industry. There were also a number of interested parties that expressed this was the main reason for disagreeing with FDA's research, calling the research task premature to updating the definition of "healthy." The majority of the

concerns relate to unintended consequences that a "healthy" label could have on consumers' health. For example, some expressed concerns that having a "healthy" label on certain foods could discourage consumers from purchasing foods that serve as important nutrient-rich foods, yet may not be labeled as "healthy" because the food does not meet the criteria of a "healthy" designation. Some raised the notion that there is "no one size fits all" solution as to what foods should be labeled "healthy" because what is healthy for one individual may not be healthy for another.

While the available information surrounding this new label symbol is limited, manufacturers and other interested parties should be aware of the risks brought by FDA's anticipated update to its regulations. This brief summary of the differing opinions involving a potential change in FDA guidance demonstrates the effect that alterations to product labeling could have to food businesses, mostly related to consumer behavior and perception. Industry participants therefore should consider the potential impacts of a "healthy" symbol and ways to integrate these changes to their product labeling and marketing, while also being cognizant of associated risks.

MAINTAINING A "HEALTHY" BALANCE IN FOOD LABELING

FDA recognizes the importance of (and encourages) industry innovation and brand developments. Industry participants should not be discouraged from innovating and sharing with consumers the characteristics of their food products. At the same time, as the examples above demonstrate, even accurate claims may spawn class action litigation from overzealous consumers (and their lawyers) who frequently stretch the bounds of what a reasonable consumer might believe about a product. Even where a company's product complies with regulations—and is accurate and truthful—or where regulations do not specifically address a claim, companies should consider whether a consumer might allege (often without basis) the claim is misleading or deceptive. With consumer fraud class actions on the rise, especially in the realm of express or implied health claims on food products, the risk of litigation is ever-present. To mitigate that risk, companies must ensure that product claims are substantiated and well-documented, comply with applicable regulations, and are not an easy target for misinterpretation.

Consumer Food Labeling Litigation—Quantity Over Quality

The plaintiffs' bar has been active and creative in engineering claims; many have failed for failure to state a claim, but plaintiffs continue to bring them, demonstrating that a quantity of lawsuits apparently has more value to the plaintiffs' bar than their quality. Food companies have seen similar cases, with almost identical claims, filed against similarly situated companies (i.e., "copycat" lawsuits). For example, in the last three years, there have been more than 200 putative consumer class actions filed alleging that manufacturers of foods like almond milk, cereals, or yogurts misled consumers into believing their products contained real vanilla bean, rather than vanilla flavor. Nearly all of the cases that courts have considered have been dismissed, with courts generally finding that the labels would lead a reasonable consumer to believe the product is vanilla-*flavored*, not that it actually contains real vanilla bean.[21] Additionally, some courts have dismissed complaints when they find no reasonable consumer could have been misled by the label.[22]

Even if these claims often lack merit, they cost a company time and money to defend, and the potential liability on claims that survive dismissal can be substantial, given that many hundreds of thousands of any given product may be sold to consumers. Thus, it is important that companies be creative and proactive in thinking about and addressing how a consumer could possibly misinterpret or misunderstand a labeling claim, taking the label as a whole into account.

Defendants have found some success in obtaining early dismissal of consumer class actions based on "preemption." Consumers typically bring state law claims in this area. Under the doctrine of preemption, state law claims will be preempted by federal food labeling laws to the extent the consumer-plaintiff seeks to impose requirements different from or in addition to federal law. If FDA regulations directly address a labeling issue and a label is in compliance, a consumer's state law claim may be preempted. Victories for food manufacturer defendants on these grounds have led plaintiffs' counsel to become savvier and to try to draft allegations that avoid a

preemption defense, claiming that a label statement is not directly governed by the FD&C Act, or that the label is misleading for reasons other than the claim specifically addressed by FDA regulation. Manufacturers should therefore consider tailoring product labeling claims to those expressly permitted by FDA's regulations.

Striking a "Healthy Balance"—Sharing and Protecting Your Brand

The litigation and regulatory landscape described above might, understandably, make food companies wary of including a nutrient content or a "healthy" claim on their labels. But avoiding every possible legal risk may cause even greater harm to a company and its brand, to say nothing of depriving consumers of helpful, accurate, and truthful information to assist in their product choice. Food labels are the primary mechanism by which consumers learn about a food product or food brand. Therefore, it is important for food companies to share their creativity and brand information both to attract consumers to the brand and to help promote FDA's goal of ensuring that consumers get the benefit of accurate and informative labeling.

Companies that avoid healthy or nutrient content claims risk leaving themselves at a competitive disadvantage. For example, as noted in a recent article, the growth of the dairy industry has lagged behind the rocket growth experienced by other products in the functional beverage industry.[23] Other functional beverages utilize packaging to communicate the nutritional benefits of their products to consumers. In contrast, milk product labels generally lack this information and consumers—particularly younger consumers who did not grow up with marketing campaigns touting milk's benefits—are less informed about milk's nutritional benefits and thus less likely to purchase it.

To best strike this balance, companies must collaborate internally across product development, marketing, regulatory compliance, and legal functions to understand both the regulatory and litigation risks associated with a particular claim, as well as the benefit that making a claim on a product's label could have on the company, its brand, and the target consumer. To best position themselves, companies should substantiate with reliable and competent evidence any claims made on a product label and internally document both the process and results when substantiating each claim. Further, while remaining creative, it is important for companies to consider the product labeling as a whole. While a single statement or image may not be misleading on its own, a consumer may argue that a collection of images or statements can be misleading. Similarly, if after balancing the risks and benefits, a company decides to include a claim on the label, it should also consider whether the label requires any clarifying information to mitigate the risk that a consumer will claim to have misinterpreted or misunderstood the information provided.

CONCLUSION / TAKEAWAYS

While still touting the nutrients and health benefits of their food and beverage products, manufacturers should take steps to minimize the risk of even unfounded litigation or regulatory enforcement. Companies should ensure that any statement or claim placed on their product's label complies with all applicable regulations, has well-documented claim substantiation, and is clear in its meaning. Be creative and maintain a skeptical eye when considering whether a claim might be misunderstood by, or deceiving to, a consumer. By the same token, companies should not be so wary of making claims that they miss an opportunity to share characteristics, innovations, and developments that are relevant and desirable to the increasingly health-conscious consumer. By collaborating across product development, marketing, regulatory compliance, and legal departments, companies can establish a "healthy" balance between a company's marketing strategies and risk tolerance.

On a going-forward basis, manufacturers should consider how a potential "healthy" symbol might impact their business and continue to monitor FDA and other relevant agency reports and actions that involve food labeling. Be prepared to evaluate how new regulations in this area could impact product formulations, branding, labeling, and marketing. And lastly, monitor food labeling litigation to keep apprised of trends and new areas of focus for consumer class actions. For example, beverage manufacturers have seen a recent increase in consumer class action challenges to sustainability, eco-friendly, and recyclability claims, and should be reviewing their labels with such claims in mind. There is a "healthy balance" to be obtained there, too.

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ENDNOTES

1 *See, e.g.*, *Campbell v. Whole Foods Mkt. Grp., Inc.*, No. 1:20-CV-01291 (S.D.N.Y.) (alleging honey graham crackers label was misleading because the word "honey" implied the crackers were sweetened only with natural honey, rather than other sweeteners); *Mason v. Reed's, Inc.*, No. 18-cv-10826 (S.D.N.Y.); *Brazil v. Dole Food Co., Inc.*, No. 12-CV-01831 (N.D. Cal.) (alleging Dole misled customers by labeling its fruit products as "All Natural Fruit" when they contain citric acid).

2 *See, e.g.*, *Francione v. The Kraft Heinz Company*, 1:21-cv-10928 (D. Mass.) (alleging that defendant-mac and cheese manufacturer misled consumers by marketing a product as healthy, with no artificial flavors or preservatives, but failed to inform consumers that the packaging contained traces of the chemical ortho-phthalate); *Franklin v. General Mills*, 2:21-cv-01781 (E.D.N.Y.) (same).

3 *FDA Nutrition Innovation Strategy*, FDA.

4 H.R. 4917.

5 FDA, *supra* note 3.

6 *Id.*

7 *Id.*

8 *Id.*

9 58 Fed. Reg. 2302 at 2374.

10 *See* 21 U.S.C. § 343*; see also* 86 Fed. Reg. 24629 at 24630 (citing FD&C Act, 21 U.S.C. 343(r)(1)(A)).

11 59 Fed. Reg. 24232, 24233 (codified at 21 C.F.R. § 101.65(d)(1)).

12 *Use of the Term "Healthy" in the Labeling of Human Food Products: Guidance for Industry*, FDA (Sept. 2016).

13 21 C.F.R. § 101.65(d)(2)(i).

14 *In re: KIND LLC "Healthy and All Natural" Litigation*, 1:15-MD-02645 (S.D.N.Y.) (consolidating 12 class action lawsuits).

15 *Statement on FDA's Actions on Labeling of KIND Products*, FDA.

16 *In re: KIND LLC "Healthy and All Natural" Litigation*, 209 F. Supp. 3d 689, 691 (S.D.N.Y. 2016).

17 FDA, *supra* note 12.

18 86 Fed. Reg. 24629.

19 *FDA In Brief: FDA Issues Procedural Notice on Potential Plans to Conduct Research About Use of 'Healthy' Symbols on Food Products*, FDA (last updated May 6, 2021).

20 Appendix G Healthy Symbol Figures.

21 *See, e.g.*, *Garadi v. Mars Wrigley Confectionery US, LLC*, No. 1:19-CV-03209, 2021 WL 2843137 (E.D.N.Y. July 6, 2021).

22 *See, e.g.*, *Becerra v. Dr Pepper/Seven Up, Inc.*, 945 F.3d 1225 (9th Cir. 2019) (finding a reasonable consumer would not be misled into believing a "diet" soda would "assist in weight loss or healthy weight management").

23 Elizabeth Crawford, *Marketing Shortfalls Hold Dairy Back from Seizing Full Potential Offered by Demand for Functional Products*, FoodNavigator-USA, (July 2, 2021).