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2022 Litigation and Regulation Trends in Labeling and Advertising for the Food and Beverage Industry

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I. Introduction

The labeling and advertising of food and beverage products is a highly regulated area, with multiple federal and state agencies directed to protect consumers from inaccurate information. Food and beverage companies are held to exacting standards on product labeling to ensure that nutritional information is accurate, and that claims made on product labels are accurate. In recent years, there has been a flood of consumer class action litigation and regulatory agency actions directed to how these companies advertise to consumers. The Biden administration is likely to increase regulation of products in this space.

II. Framework: How Is Food and Beverage Labeling Regulated?

A. Federal Government

Regulating labeling requirements for food and beverage products is within the purview of the federal government, rather than the state of local level. Two agencies are primarily responsible for regulating the labeling of food and beverage products.

1. Food & Drug Administration ("FDA")

The FDA regulates food labeling under the statutory authority of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.

The FDA "has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce." MOU with Federal Trade Commission Concerning Exchange of Information (FDA-225-71-8003), available at https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003.

The "misbranding" of food is regulated by 21 U.S.C.A. § 343. That statute states that a food shall be deemed to be misbranded if it has any of the following:

- False or misleading label
- Offer for sale under another name
- Imitation of another food (unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated)
- Misleading container
- Package form without having an accurate label containing name of manufacturer, accurate statement of what the package contains
- Prominence of information on label (if it does not comply with FDA rules on the need for conspicuous labeling of certain ingredients)
- Representation as to definition and standard of identity
- Representation as to standards of quality and fill of container
- Representation for special dietary use
- Artificial flavoring, artificial coloring, or chemical preservatives (will be considered misbranded if it does not have a clear label stating that the flavoring is artificial)

In May 2016, the FDA announced a final rule for the revision of the nutrition and supplements food labels, which overhauled what information needed to be on food labels. That complex, 258-page rule set the standards for what food manufacturers need to include in nutrition labels.

2. U.S. Department of Agriculture Food Safety and Inspection Service ("FSIS")- regulates the labeling of meat, poultry, and egg products

The FSIS "is the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry and processed egg products are safe, wholesome and correctly labeled and packaged."

While FDA regulations are more general as to what manufacturers should include, FSIS regulations are very specific and targeted to consumer knowledge and safety about this subset of products. FSIS Compliance Guideline for Label Approval July 2020, available at https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES

Some examples of FSIS labeling rules include:

- Requirement that poultry may not be labeled "fresh" unless whole poultry and cuts have never been below 26 °F.
- Requirement for meat processors to disclose mechanical tenderization and give safe cooking instructions to consumers.
- FSIS final rule requiring that the source of natural sausage casings be disclosed on the product label if the casings are derived from a different type of meat or poultry than the meat or poultry encased in the sausage.

III. Framework: How Is Food and Beverage Advertising Regulated?

A. Federal Level

1. Federal Trade Commission

Since 1954, the FTC and the FDA have operated under a Memorandum of Understanding, under which the FTC takes primary responsibility for regulating food advertising, while FDA has primary responsibility for regulating food labeling.

The FTC's authority to regulate food and beverage advertising comes from the FTC Act. Section 5 of the FTC Act prohibits "unfair or deceptive acts or practices." Sections 12 and 15 of the FTC Act prohibit "any false advertisement" that is "misleading in a material respect."

What constitutes a deceptive advertisement?

The FCTC's Deception Policy Statement says: "An advertisement is deceptive if it contains a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. Although deceptive claims are actionable only if they are material to consumers' decisions to buy or use the product, the Commission need not prove actual injury to consumers."

FTC administrative actions against unfair or deceptive food and beverage advertising has included the following:

- Cease and desist orders
- Corrective advertising
- Direct notification to consumers
- Trade name excision
- Consumer disgorgement or redress
- Civil penalties
- Administrative consent

However, the most high profile cases have generally not been focused on the food and beverage industry, although supplements have been targeted for some of these actions. For

example, there were some high profile warning letters and a settlement involving companies that claimed to offer protection against COVID-19.

B. State Level: Consumer Protection Statutes

Most states have their own consumer protection statutes to protect consumers from false advertisements. California and New York have particularly strong consumer protection laws and strong plaintiffs' bars, which have resulted in a slew of food and beverage adverting lawsuits.

IV. Recent Administrative Developments

A. FDA to Investigate and Issue Guidance on "Healthy" Labeling

On March 25, 2022, the U.S. Food and Drug Administration ("FDA") announced a public process to update the "health" nutrient content claim for food labeling. This process will include the agency's review of a voluntary symbol that could be used to convey that a product meets the criteria for the nutrient content claim "healthy."

The FDA issued a request for information on "healthy" labeling more than five years ago on September 28, 2016 and held a public meeting on March 9, 2017, but did not issue a new proposed rule. Until FDA issues guidance, food manufacturers can continue to use the term "healthy" on foods that meet the current regulatory definition.

Under the 2016 guidance, food manufacturers may use the implied nutrient content "healthy" on products which (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.

FDA also issued a 30-day procedural notice that it would be conducting quantitative consumer research on voluntary symbols that could be used to convey the nutrient content claim

"healthy." This notice builds on a previous notice, issued on May 2021 and incorporates the comments received in 2021.

The potential symbol would be a stylized representation of the nutrient content claim "healthy," and would be used along with a proposed rule that would update when manufacturers may use the "healthy" nutrient content claim on food packages.

B. FTC Seeks Record Penalties for Deceptive Environmental Claims

On April 8, 2022, the Federal Trade Commission ("FTC") announced that it was using its Penalty Offense Authority to seek a $5.5 million penalty for deceptive environmental claims against Kohl's, Inc. ($2.5 million) and Walmart, Inc. ($3 million).

The FTC charged both companies with falsely marketing dozens of rayon textile products as bamboo and with claiming that the bamboo textiles were made using eco-friendly processes when the process actually used toxic chemicals and resulted in hazardous pollutants.

The proposed orders settling the FTC's complaints against Kohl's and Walmart require that the companies:

- Stop claiming that a textile product is made of bamboo or bamboo fiber, unless they can substantiate it;
- For products made of bamboo or bamboo fiber, stop claiming that it is produced free of harmful chemicals, using non-toxic materials, or in a way that is safe for the environment or non-polluting, or has any other environmental benefits because it is derived from bamboo, unless they can substantiate it;
- Stop violating the FTC's Textile Act and Rules by deceptively advertising textile contents; and

- Pay $5.5 million in penalties: Kohl's and Walmart must pay civil penalties of $2.5 million and $3 million, respectively, under the FTC's Penalty Offense Authority.

This action suggests that the FTC will continue to penalize companies for eco-friendly and "green" marketing claims. The FTC's consumer guidance states: "Many companies make claims and design packages that promote their products as safe for people or the environment. The law requires these "eco-friendly" or "green" claims to be truthful, and the FTC's Green Guides tell businesses how to comply with the law when they make environmental claims." Food and beverage companies making similar packaging claims must closely follow FTC guidance and evaluate claims about packaging and sustainability.

C. FTC's Made in USA Rule

Since 1998, the FTC has had a "Made in USA" standard regulating when companies can make unqualified claims that a product is Made in the USA. In June 2020, the agency announced a proposed new Made in USA rule with increased enforcement ability. The rule was finalized on July 14, 2021

The FTC's final rule makes it an unfair or deceptive act to make an unqualified claim that a product as Made in the USA (or any variation) unless three things are true about the product: (1) The final assembly or processing of the product occurs in the United States; (2) all significant processing that goes into the product occurs in the United States; and (3) all or virtually all ingredients or components of the product are made and sourced in the United States

The rule covers not only product labels, but also "materials, used in the direct sale or direct offering for sale of any product or service, that are disseminated in print or by electronic means, and that solicit the purchase of such product or service by mail, telephone, electronic mail, or some other method without examining the actual product purchased" that "include[] a

seal, mark, tag, or stamp labeling a product Made in the United States." The rule also gives the FTC enforcement authority to fine companies that are found to violate this rule, with a fine of up to $43,280 for each violation.

The FTC's first action under the 2021 rule was announced on April 13, 2022. The agency filed a complaint against Lithionics Battery for marketing battery products with a U.S. flag image and the words "Made in U.S.A." when those products incorporated significant imported components. FTC is seeking a $105,319.56 penalty in that case.

D. FDA Uniform Compliance Date for 2021-2022 Regulations

On January 14, 2021, the FDA announced that January 1, 2024, will be the uniform compliance date for final food labeling regulations issued in calendar years 2021 and 2022. Existing requirements for compliance dates contained in final rules published before January 1, 2021 will not change.

V. Lanham Act Litigation

The Lanham Act allows federal civil lawsuits for false advertising that "misrepresents the nature, characteristics, qualities, or geographic origin" of goods or services. 15 U.S.C. § 1125(a). Many lawsuits under the Lanham Act are brought by competitors. Courts were conflicted about whether permitting federal lawsuits for advertising of food and beverage products would preempt the FDA's authority. However, in 2014, the Supreme Court unanimously held that the FDCA did not preclude food and beverage labeling claims under the Lanham Act.

The Court held: "The structures of the FDCA and the Lanham Act reinforce the conclusion drawn from the text. When two statutes complement each other, it would show disregard for the congressional design to hold that Congress nonetheless intended one federal statute to preclude the operation of the other. The Lanham Act and the FDCA complement each

other in major respects, for each has its own scope and purpose. Although both statutes touch on food and beverage labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety. The two statutes impose "different requirements and protections."

The two statutes complement each other with respect to remedies in a more fundamental respect. Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA. The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis. By "serv[ing] a distinct compensatory function that may motivate injured persons to come forward," Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, "provide incentives" for manufacturers to behave well. Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 115–16 (2014) (internal citations omitted).

We have seen a few cases over the last few years wherein a smaller shop brings a lawsuit under the Lanham Act to prevent a larger corporation from taking advantage of their name and trademarks. For example, in 2020, a restaurant owner filed a class action lawsuit against Grubhub alleging a single cause of action against Grubhub for violation of the Lanham Act. *See*

Co Craft LLC dba Freshcraft v.GrubHub Inc., Case No. 1:20-cv-01327 (D. Colo). Plaintiff Freshcraft alleged that Grubhub falsely advertised on its platform that certain restaurants not partnered with Grubhub were either closed or not accepting online orders so as to steer customers to competing restaurants that were partnered with Grubhub. A parallel class action lawsuit was filed against Grubhub in the Northern District of Illinois in October 2020. *See Lynn Scott, LLC et al. v. Grubhub Inc.*, Case No. 20-6334 (N.D. Ill). Plaintiffs in this action also alleged a single cause of action under the Lanham Act against Grubhub, however they took more of a trademark angle, alleging that Grubhub violated the Lanham Act by adding popular local restaurants to their site and using the restaurants' names and logos without permission. Neither case has been resolved yet. In Spring 2021, it looked like Freshcraft and Grubhub had reached a preliminary settlement, which stayed the Lynn Scott matter. However, plaintiffs in *Lynn Scott* sought to intervene and oppose preliminary approval of the proposed class action settlement. So far it does not look like a court has ruled on the motion for preliminary approval.

There was resolution, recently, in a Lanham Act case in the Southern District of California in San Diego. On March 30, 2022, a jury found that an international beer conglomerate's marketing of one of its drinks infringed on the trademark of a smaller, independent craft brewery. The case, *Stone Brewing Co., LLC v. Molson Coors Brewing Co., et al.*, Case No. 18-cv-00331 (S.D. Cal.), was brought by plaintiff Stone Brewing, an independent craft brewery based in San Diego, against defendant Molson Coors Brewing Company and related entities, alleging, among other things, that Molson Coor's rebranding of its Keystone beer infringed on Plaintiff's "STONE" trademark.

Named after a ski resort in Colorado, the original branding for Molson Coor's Keystone beer clearly stated "Keystone" on the cans, with a depiction of a mountain range in the

background. In 2017, however, Molson Coors updated the branding by dropping the mountain logo and essentially dropping "Key" from its name, instead emphasizing "STONE" on the product's cans, packaging, as well as in several social media posts. According to Stone, this was a thinly-veiled attempt to both diminish Stone's trademark rights in the "STONE" trademark as well as an attempt to capitalize on Stone's reputation and image as a premiere independent craft brewery. The jury ultimately agreed with stone, finding that Molson Coors had infringed on Stone's "STONE" trademark and awarding Stone $56,000,000 in damages. The jury did not find, however, that Molson Coor's infringement was willful.

VI. Litigation and the Reasonable Consumer Standard

"Claims" made in advertising or promotional materials across a wide range of platforms can give rise to allegations of false advertising by consumers, competitors, or the government.

In order for an advertising claim to be made, the claim must be both factual and material. Advertising claims can be proved false in several ways, including the claim being literally false; false by way of necessary implication; literally true but misleading.

Courts have applied a reasonable consumer test, which is key to determining if a product's advertising and labeling is potentially misleading. The reasonable consumer test is meant to be objective, and to ask the question of whether an advertisement would mislead an objectively reasonable consumer, not whether the actual plaintiff was or was not misled.

The reasonable consumer standard requires a probability that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.

The Ninth Circuit has found that the reasonable consumer test requires litigants to show that "members of the public are likely to be deceived" by a product's advertisements. *Williams v. Gerber Prod. Co.*, 552 F.3d 934, 938 (9th Cir. 2008).

One interesting aspect of the reasonable consumer standard is that it can be tailored to a specific product, if warranted. For example, last year, the Ninth Circuit upheld the dismissal of a false advertising lawsuit concerning manuka honey sold by Trader Joe's. *See Moore et al. v. Trader Joe's Co.*, Case No. 19-16618 (9th Cir.). Plaintiff had argued that Trader Joe's falsely labeled its Manuka honey as "100% New Zealand Manuka Honey" when, in reality, only about 57-62% of the honey is derived from Manuka nectar. Since manuka honey contains an organic compound believed to have notable health benefits, the honey is in high demand and often sells at a much higher price than other honeys. The Ninth Circuit determined the label properly adhered to the FDA's "honey guidelines" laid out in the FDCA (namely that the honey can claim the name of a plant or blossom if it's a "chief floral source" of the honey), as the honey is 57-62% derived from Manuka nectar. When determining if the "100% New Zealand Manuka Honey" label would confuse a reasonable consumer, the court considered the label from the perspective of a reasonable consumer of *Manuka honey*, rather than just a generic reasonable consumer. The Court reasoned that anyone who actively sought out Manuka honey would have the knowledge to notice a number of contextual inferences from Trader Joe's label to determine that the "100%" claim did not mean the honey was 100% derived from the Manuka plant, including the fact that it is impossible to make honey derived from one floral source as humans cannot control bees' natural foraging behavior, Trader Joe's Manuka honey is far too inexpensive to be anywhere close to 100% from the Manuka plant, and that Trader Joe's label clearly lists the honey's rating on the Unique Manuka Factor scale, indicating to a reasonable

Manuka honey consumer that the honey was not 100% derived from the Manuka plant. Given how niche Manuka honey is, someone who would seek out Manuka honey and read this label was expected to have this knowledge. With this ruling, the Ninth Circuit at least accepts the proposition that niche products attract niche reasonable consumers.

A recent Seventh Circuit decision held that average consumers should not be held to be responsible to closely parse labels rather than being able to rely on front of the box claims. "Consumer-protection laws do not impose on average consumers an obligation to question the labels they see and to parse them as lawyers might for ambiguities, especially in the seconds usually spent picking a low-cost product. *See, e.g., Danone, US, LLC v. Chobani, LLC*, 362 F. Supp. 3d 109, 123 (S.D.N.Y. 2019) ("[A] parent walking down the dairy aisle in a grocery store, possibly with a child or two in tow, is not likely to study with great diligence the contents of a complicated product package, searching for and making sense of fine-print disclosures ... . Nor does the law expect this of the reasonable consumer.")." *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468, 476 (7th Cir. 2020)

Similarly, a court in the Northern District of California not too long ago determined that a reasonable consumer is not expected to rifle through a company's website to verify claims made in advertisements. *See Friends of the Earth, et al. v. Sanderson Farms, Inc.*, Case No. 3:17-cv-03592 (N.D. Cal.). The court specifically noted that the reasonable consumer standard does not require consumers to "be private investigators[.]"

That being said, courts will still require a reasonable consumer to do at least some research if the label in question is ambiguous. For example, a federal judge in the Southern District of New York dismissed a fraud and misrepresentation action against Bimbo Bakeries USA, Inc., a food company whose brands include Sara Lee, Brownberry, and Entemann's. *See*

Monica Boswell v. Bimbo Bakeries USA Inc., Case No. 1:20-cv-08923 (S.D.N.Y.). Plaintiff brought an action against Bimbo, alleging that defendant fraudulently advertised one of its products as an "All Butter Loaf Cake" when, in reality, the cake includes other ingredients in addition to butter, such as soybean oil and artificial flavors. The Court ultimately granted a motion to dismiss the complaint, determining that a reasonable consumer would not be misled by the phrase "All Butter" in the label. The court determined that the label itself was ambiguous because it was susceptible to multiple interpretations as well as the fact that a reasonable consumer would know that the phrase's literal meaning-that the loaf cake is in fact "all butter"-would in all likelihood be impossible. As the label was ambiguous, a reasonable consumer would be expected to do a bit more investigating to resolve the ambiguity, namely reading through the additional information provided on the packaging, including the ingredient panel. Upon reviewing the ingredient panel, the reasonable consumer would necessarily see that the product included other ingredients in addition to butter. The phrase "All Butter," as a result, was determined to not be misleading in this context.

VII. Food and Beverage Labeling and Advertising: Recent Cases

A. Coca-Cola Beats Artificial Flavor Lawsuit

On August 31, 2021, the Court of Appeals for the Ninth Circuit issued an unpublished order revoking class certification of a consumer class in a Coca-Cola labeling case. The plaintiffs alleged that Coke's advertising slogan of "no artificial flavors, no preservatives added since 1886" was misleading because Coke contains phosphoric acid.

This decision reversed a class certification order from a California federal judge. The court held that the plaintiffs lacked standing to pursue injunctive relief because they had failed to demonstrate harm and thus had not adequately alleged an injury in fact.

Under Ninth Circuit precedent, “a previously deceived consumer may have standing to seek an injunction against false advertising or labeling, even though the consumer now knows or suspects that the advertising was false at the time of the original purchase, because the consumer may suffer an ‘actual and imminent, not conjectural or hypothetical’ threat of future harm.” The court found that the plaintiffs in this case did not meet this standard.

The court also held that plaintiffs’ expressed desire for Coca-Cola to truthfully label its products, without more, was “insufficient to demonstrate that they have suffered any particularized adverse effects,” as required by the governing case law.

B. Arrowhead Water Image Lawsuit

On October 22, 2021, the Court of Appeal for the Ninth Circuit issued an unpublished opinion affirming dismissal of consumer false advertising claims against Nestlé’s Arrowhead brand water based on the mountain image at the front of the Arrowhead label.

The plaintiff argued that she believed the mountain printed on the front of the Arrowhead label to be "Arrowhead Mountain," and on the basis of that belief, determined that "NESTLÉ Product was [sourced exclusively] from the springs in the arrowhead mountain."

The Court rejected this agreement and found that there was not “any indication that the image of the mountain and lake refer to any specific mountain or lake.” Instead, the image of the mountain and lake would lead a reasonable consumer to believe “the true statement that Arrowhead Water is comprised entirely of mountain spring water.”

The Court noted that the Ninth Circuit’s reasonable consumer standard was the appropriate way to evaluate the claims and held that the facts presented the “rare case where this Court may conclude on the pleadings that no reasonable consumer would be misled by any of the product labels at issue in this suit.”

C. Vanilla Labeling

This is the largest number of class actions filed regarding a single word. The category of allegedly deceptive "vanilla" claims, alleging that defendants' "vanilla"-labeled products contain flavoring ingredients that do not come from vanilla beans. Claims against Wegmans vanilla ice cream, Westbrae Natural's Organic Unsweetened Vanilla Soymilk and Blue Diamond's vanilla almond milk have been dismissed already, and we expect many more will follow.

D. Diet Soda Advertising Lawsuits Falter

Plaintiffs in New York and California brought a series of consumer lawsuits targeting diet soda brands. These lawsuits alleged that the use of the word "diet" in advertising and selling diet soda was misleading because consumption of these products did not lead to a healthier lifestyle or weight loss, and in fact could be tied to weight gain. Those cases were filed in 2017 by plaintiffs who claimed the diet soda products (including Coke Zero, Diet Coke, Diet Snapple, and Diet Pepsi) caused them weight gain and that the advertising was deceptive because it used fit models and suggested that use of the diet soda would contribute to health and nutrition.

The Second Circuit affirmed the dismissal of all consumer fraud cases in New York against diet soda brands in multiple decisions in the summer of 2019. The Court held that, in the context of soft drinks, the term "diet" refers to calorie content, and it has no absolute meaning, such that in order to meet federal advertising standards, a diet soft drink need only have fewer calories than its non-diet version.

Separately, California consumers filed consumer fraud lawsuits against the Coca-Cola Company and Dr. Pepper/Seven Up for false advertising in Diet Coke and Diet Dr. Pepper. The case against Coca-Cola was dismissed on jurisdictional grounds in December 2019. On December 30, 2019, the 9th U.S. Circuit Court of Appeals dismissed the claims against Dr.

Pepper. Ultimately, the court held that no reasonable consumer would assume that the use of the word "diet" in Diet Dr Pepper promised weight loss or weight management. Rather, the court found that diet soft drinks were common in the marketplace and the prevalent understanding of the term in that context was simply that the "diet" version of a soft drink has fewer calories than the "regular" version of that drink. In describing the applicable reasonable consumer test, the 9th Circuit found that it required more than a "mere possibility" that Diet Dr Pepper's label "might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner." Instead, the reasonable consumer standard requires a probability "that a *significant portion* of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled."

The Ninth Circuit and the Second Circuit's clear and uniform rulings on this line of cases set a precedent that the reasonable consumer's understanding of the term "diet" in the context of the beverage industry is related to calories rather than the overall effect of the product on a healthy diet.

E. Angus Steak Breakfast Sandwiches Not Misleading

Dunkin' Donuts was sued in a class action lawsuit over its Angus steak breakfast sandwiches. Plaintiffs alleged that "through representations made in labeling and television advertisements, Dunkin Donuts deceived consumers into believing that the Products contained an 'intact' piece of meat when the Products actually contained an "inferior product" with multiple additives." Plaintiffs claimed that this advertising practice violated New York state consumer protection laws and implied to customers that the Angus steak sandwich was a superior product as compared to other Dunkin' Donuts products. On March 31, 2020, the U.S. Court of Appeals for the 2nd Circuit dismissed the lawsuit, holding that no "reasonable

consumer" could have been misled by Dunkin' Donuts advertising, which showed close-ups of the product itself. Based on the price of the sandwich and the fact that it was marketed as a "grab-and-go" breakfast item, a reasonable consumer would not have expected a piece of steak for a $3.99 breakfast sandwich. Notably, Dunkin' Donuts took the Angus steak sandwich off its menu as the litigation was pending.

F. Front of the Box vs. Back of the Box Labels for the Reasonable Consumer

In December 2020, the Seventh Circuit reversed a district court's dismissal of a class action false advertising complaint based on a 100% grated parmesan cheese label on the front of a product. The Court held that the fact that the accurate information on the ingredient list showing components other than the parmesan cheese did not preclude a reasonable consumer from being deceived by a "100% Grated Parmesan Cheese" front label claim. *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468, 476 (7th Cir. 2020).

In a similar case, Kellogg Co. was sued over "Whole Grain" labeling of Cheez-It crackers. The front of the Cheez-It box said the products were "made with whole grain" in bold letters. However, the crackers contained a small amount of whole grain and were primarily made with enriched white flour. The district court initially found that the labels would not mislead a reasonable consumer because it was factually accurate in that there was some whole grain in the crackers. The court further found that the ingredient label was accurate, and a reasonable consumer would have reviewed that label. The Second Circuit reversed the lower court and held that the product was likely to mislead a reasonable consumer because the product was made with significantly more enriched white flour than whole grain. The court also agreed with the Ninth Circuit that a "reasonable consumer should not be expected to consult the Nutrition Facts panel on the side of the box to correct misleading information set forth in large

bold type on the front of the box." *Mantikas v. Kellogg Co.*, 910 F.3d 633, 637 (2d Cir. 2018)The court held that it would be an improper precedent for companies to be able to use a tiny portion of an ingredient to justify labeling the product inaccurately.

VIII. Litigation Trends

A. Where Are These Lawsuits Filed?

According to the U.S. Chamber Institute for Legal Reform, "three-quarters of food class actions in federal courts are in four states: California (36%), New York (22%), Florida (12%), and Illinois (7%). Another 10% of cases are spread among federal courts in Missouri, New Jersey, and Pennsylvania. Plaintiffs' lawyers file very few food class actions in other jurisdictions." U.S. Chamber Institute for Legal Reform, The Food Court (February 2017), available at https://instituteforlegalreform.com/wp-content/uploads/2020/10/TheFoodCourtPaper_Pages.pdf.

B. Trending Claims

1. "All-Natural"

There's been a lot of confusion over the last few years over the proper use of the term "natural" as its meaning has not yet been defined by the FDA. The FDA requested public comment on the use of the term in October 2018 but has not finalized a definition. In all likelihood, until the FDA provides clarification as to what makes a product "natural," companies will continue to struggle with determining how they can advertise their products. Courts, too, would likely welcome any guidance from the FDA. Given the lack of guidance, whenever a false advertising case surrounding the use of the term "natural" is filed, the parties will often settle, rather than risk litigation. One example is *Megan Holve v. McCormick & Company, Inc.*, Case No. 6:16-cv-06702-FPG (W.D.N.Y.). Originally filed as a putative class action in October 2016,

plaintiff alleged that McCormick misrepresented several varieties of its spcies and seasoning products by labeling them as "natural" when in reality they contained synthetic, artificial and/or genetically modified ingredients, including corn starch, white corn flower and citric acid. The products at issue include, among others, McCormick's Brown Gravy Mix, Fiesta Citrus Seasoning, and its Southwest Seasoning, all of which are labeled "natural" on the front of the packaging." On McCormick's motion, the court agreed to stay the matter for more than two years so as to provide the FDA time to issue further guidance as to the meaning of "natural." When that guidance never came, however, the case resumed in 2020. The parties ultimately settled the matter, obtaining final approval of the class action settlement earlier this year.

Many hoped there would be more guidance issued under the Biden administration, and there still may be yet. But so far, the FDA still hasn't provided any guidance regarding the meaning of "natural." Until courts and companies have that guidance, we'll likely see more settlements like this one.

2. Added Sugar

There's been several recent settlements in class action cases concerning cereals that make health and wellness claims on their boxes when the cereals contain added sugar. Two of the biggest settlements were in *Debbie Krommenhock et al. v. Post Foods, LLC*, Case No. 3:16-cv-04958-WHO (N.D. Cal.) and *Stephen Hadley et al. v. Kellogg Sales Co.*, Case No. 5:16-cv-04955 (N.D. Cal.). There are a lot of similarities between the two cases. In *Krommenhock*, the plaintiffs allege that Post violated California consumer protection laws by deceptively marketing high-sugar cereals with health and wellness claims. The lawsuit specifically targets representations made regarding more than 50 of Post's cereals, including Post's Great Grains Cranberry Almond Crunch, Post's Select/Great Grain Raisins, dates, and Pecans, and Honey

Bunches of Oats. The parties settled the action for $15 million and injunctive relief. In addition to making the payment, Post agreed to stop making claims on cereal like "no high fructose corn syrup," "less processed," "wholesome," "smart," and "nutritious" on products where 10% or more of the calories come from sugar. They obtained final approval of the class action settlement in June 2021.

Hadley had similar facts, except this time it was against Kellogg's cereals. Examples of the misrepresentations at issue in this matter are that Raisin Bran is "Heart Healthy" or Frosted Mini-Wheats is "Lightly Sweetened" and "Nutritious and Delicious, You can have it both ways!" The parties also ultimately settled this matter. Kellogg agreed to make a class payment of $13 million as well as discontinuing certain claims on certain cereals, including "Heart Healthy," "Healthy," and "Lightly Sweetened."

This is another example of settlements arising out of confusion regarding the definition of a marketing term. Here, the term is "healthy." Until the FDA provides further guidance, confusion and class actions are likely to continue.

3. Country of Origin

On April 20, 2022, a $15 million class action settlement was approved by the court in *Hesse, et al. v. Godiva Chocolatier, Inc*. Plaintiffs alleged that the company's use of "Belgium 1926" as a marketing phrase led consumers to believe that chocolates were produced in Belgium rather than in Pennsylvania. The class is made up of individuals who purchased any of the covered Godiva chocolate products between January 31, 2015 and October 26, 2021. Plaintiffs' attorneys may seek up to $5 million in legal fees and costs.

IX. Takeaways for the Industry

A. **Product Close-Ups**: products advertised with images of the product, even if contrary to the labeling, tended to meet the reasonable consumer test, because the consumer viewing the advertising is able to see what the product looks like.

B. **Front vs. Back of the Box**: Even in cases where products were accurately labeled in the product ingredients section of the packaging, contradictory claims advertising inaccurate position that is prominently featured may violate the reasonable consumer standard. Cases in the Ninth Circuit, Second Circuit, and more recently the Seventh Circuit have held that even if all the labeling requirements were complied with and the ingredients label and nutritional facts would have informed the consumer about the truth of the product, consumers were not required to study the label.

C. **Get Out the Dictionary**: Courts have delved into the dictionary definition of words, and found that if a label or advertisement matches one common definition, then a reasonable consumer will not be deceived. For example, in the Dunkin' Donuts breakfast sandwich case, the court found that one definition of "steak" included ground meat.

D. **Price Matters**: For products such as the Angus steak breakfast sandwich and white truffle olive oil made with no white truffles, courts were persuaded that a reasonable consumer would have any expectations buoyed by the price of the product.

E. **Role of Consumer Opinion**: In *Bell v. Publix* (the grated parmesan case), the Seventh Circuit considered consumer surveys as some evidence of what the reasonable consumer was thinking. However, judges in the Northern District of

California also rejected plaintiff's survey-based arguments which sought to remedy deficient pleadings. Time and time again, in dismissing claims related to Mott's applesauce, Ghirardelli baking chips, and Westbrae soymilk, the Northern District of California reaffirmed that consumer surveys alone do not make plausible an allegation that reasonable consumers are misled where the complaint has not otherwise plausibly alleged deception

FDA ISSUES NEW DRAFT GUIDANCE ON ALLERGENS

04.22.2022
Legal Bites

PROFESSIONALS

Pooja S. Nair

PRACTICE AREAS

Food, Beverage and Hospitality

On April 18, 2022, the U.S. Food and Drug Administration ("FDA") issued draft guidance for stakeholders on evaluating the public health importance of food allergens other than the current major food allergens identified by U.S. law.

The current major food allergens recognized by law are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans. Those allergens must be listed on the labels of packaged foods. Sesame will become the ninth major food allergen on January 1, 2023.

The new draft guidance is part of FDA's effort to evaluate emerging evidence about non-listed food allergens in a consistent and transparent manner to inform potential future actions.

The draft guidance is focused on immunoglobulin E antibody (IgE)-mediated food allergies, which are considered the most severe and immediately life-threatening food allergies. The guidance provides a framework for assessing the scientific evidence to decide if FDA should prioritize an allergen as being important for public health. The guidance is not clear on what steps the agency would take next for priority allergens.

The Center for Science in the Public Interest criticized the draft guidance for falling "short in giving consumers the protection we expect" and for "conspicuously fail[ing] to indicate when the agency would actually act" on scientific evidence to decide if a food allergen requires labeling or other consumer protections.

Written comments to the draft guidance are due by August 17, 2022 and can be submitted here.

FDA TO INVESTIGATE AND ISSUE GUIDANCE ON "HEALTHY" LABELING

04.01.2022
Legal Bites

PROFESSIONALS

Pooja S. Nair

PRACTICE AREAS

Food, Beverage and Hospitality

On March 25, 2022, the U.S. Food and Drug Administration ("FDA") announced a public process to update the "health" nutrient content claim for food labeling. This process will include the agency's review of a voluntary symbol that could be used to convey that a product meets the criteria for the nutrient content claim "healthy."

The FDA issued a request for information on "healthy" labeling more than five years ago on September 28, 2016 and held a public meeting on March 9, 2017, but did not issue a new proposed rule. Until FDA issues guidance, food manufacturers can continue to use the term "healthy" on foods that meet the current regulatory definition.

Under the 2016 guidance, food manufacturers may use the implied nutrient content "healthy" on products which (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.

FDA also issued a 30-day procedural notice that it would be conducting quantitative consumer research on voluntary symbols that could be used to convey the nutrient content claim "healthy." This notice builds on a previous notice, issued on May 2021 and incorporates the comments received in 2021.

The potential symbol would be a stylized representation of the nutrient content claim "healthy," and would be used along with a proposed rule that would update when manufacturers may use the "healthy" nutrient content claim on food packages.

Consumer class action litigation about "healthy" claims in food and beverage products has proliferated in recent years, so additional FDA guidance will be an important factor in future resolution of these cases.

FDA ANNOUNCES NEW PRIORITIES FOR GUIDANCE

02.07.2022
Legal Bites

PROFESSIONALS

Pooja S. Nair

PRACTICE AREAS

Food, Beverage and Hospitality

On January 31, 2022, FDA released a list of draft and final guidance topics that are a priority for the FDA Foods Program to complete during the next 12 months.

The guidance topics include several focused on plant-based labeling, so companies making these products should pay close attention to developments. Several topics are focused on food safety and risk reduction so are specific to developing guidance on action levels for lead and arsenic in juice and prevention of some specific foodborne illnesses. Other topics could have a significant effect on product labeling and claims.

Some of the guidance topics include:

- Labeling of plant-based milk alternatives;
- Labeling of plant-based alternatives to animal-derived foods;
- Foods derived from plants produced using genome editing;
- Questions and answers about dietary guidance statements in food labeling;
- Policy regarding certain new dietary ingredients and dietary supplements subject to the requirement for pre-market notifications; and
- Classifying food as ready-to-eat or not ready-to-eat.

FDA stated: "[w]e currently intend to develop guidance on each topic; however, the FDA Foods Program is neither bound by this list of topics nor required to issue every guidance document on this list. Several factors may impact FDA's ability to issue the listed guidance, including, for example, new Administration priorities, emerging public health issues, or other extenuating circumstances. We are not precluded from issuing guidance documents on topics not on this list."

FDA FOCUSES ON FOOD SAFETY TO BEGIN IN 2022

01.01.2022
Legal Bites

PROFESSIONALS

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PRACTICE AREAS

Food, Beverage and Hospitality

In January 2022, FDA announced new initiatives focused on food safety, indicating that the agency will continue to prioritize that area. Several of these programs are designed to provide more transparency and more information on foodborne illnesses and food safety hazards directly to consumers. Others, including a new egg regulatory program and a proposed rule on pre-market notification for food contact substances, are more technical and industry-focused.

- On January 5, FDA announced its new public-facing reportable food registry. The RFR public data dashboard contains 10 years of data from September 2009 to 2019 and covers 28 commodities and 20 food safety hazards. Unlike previous RFR annual reports, the new dashboard allows users to interact with the data points to gather more customized information at any time to find answers to their specific questions.

- On January 14, FDA announced new egg regulatory programs standards ("ERPS") designed to improve the safety of eggs and egg products. The agency's press release states: "The standards are designed to integrate the regulatory activities of partner agencies into an efficient and effective process for improving egg and egg product safety in the U.S." The program standards are for egg and egg product regulatory programs, not for manufacturers or growers of eggs. The ERPS is comprised of 10 individual standards: regulatory foundation, training program, inspection program, inspection audit program, egg-related illness, outbreak and emergency response, compliance and enforcement program, outreach activities, program resources, program assessment and laboratory support.

- Also on January 14, the Interagency Food Safety Analytics Collaboration ("IFSAC"), which is a collaboration between FDA, the Centers for Disease Control and Prevention ("CDC"), and the USDA's Food Safety and Inspection Service ("FSIS") published its priorities for 2022-2023. These priorities include analyzing trends in foodborne disease outbreaks and assessing the frequency of multi-year outbreaks. Most importantly, IFSAC will continue publishing annual reports on foodborne source attribution for

four priority pathogens: Salmonella, Escherichia coli O157, Listeria monocytogenes and Campylobacter.

- On January 25, 2022, FDA proposed a new rule to amend existing regulations on when and how FDA may determine that a pre-market notification for a food contact substance is no longer effective. According to the agency's press release, the proposed rule would "among other things, allow the FDA additional flexibility in how it determines that an FCN is no longer effective and help ensure that FDA's inventory of effective FCNs is currently based on use and safety. Primarily, this rule would enable the FDA to determine that an FCN is no longer effective when the manufacturer discontinues its use based on reasons other than safety, for example, they no longer produce, supply, or use the food contact substance." The agency is accepting public comment on the proposed rule until April 11, 2022.The rule can be reviewed here.

- On February 16, 2022, FDA will host a webinar on food safety culture in collaboration with the non-profit Stop Foodborne Illness. The webinar is entitled: "Making Leaders Risk Aware and Push to Reduce Risks" and is focused on food industry compliance leaders in the public and private sectors. This webinar is the second in a webinar series between the two organizations. Registration information is available here.

FDA Issues Final Rule for Lab Accreditation for Food Testing

12.09.2021
Legal Bites

Professionals

Pooja S. Nair

Practice Areas

Food, Beverage and Hospitality

On December 1, 2021, the U.S. Food and Drug Administration ("FDA") issued a final rule establishing the Laboratory Accreditation for Analyses of Food ("LAAF") program.

FDA will utilize the LAAF program to recognize accreditation bodies that will accredit food testing laboratories to specified standards. The final rule outlines eligibility requirements for both accreditation bodies and laboratory facilities. The LAAF program will mark a major shift in food testing, which is currently handled by private laboratories with limited government oversight.

After the LAAF program is fully implemented, testing in LAAF-accredited facilities will be required if:

- to support removal of a food from an import alert through successful consecutive testing requirements;
- to support admission of an imported food detained at the border because it is or appears to be in violation of the Federal Food, Drug, and Cosmetic Act;
- required by existing FDA food safety regulations, when applied to address an identified or suspected food safety problem (i.e., certain tests of shell eggs, sprouts, and bottled drinking water);
- required by a directed food laboratory order, a new procedure being implemented in this final rule that will allow the FDA to require use of a LAAF-accredited laboratory to address an identified or suspected food safety problem in certain, rare circumstances; and
- conducted in connection with certain administrative processes such as testing submitted in connection with an appeal of an administrative detention order.

The FDA's press release states: "[t]he establishment of the LAAF program will improve the FDA's capacity to protect U.S. consumers from unsafe food by improving the accuracy and reliability of certain food testing through the uniformity of standards and enhanced oversight of participating laboratories."

COURT REJECTS FALSE ADVERTISING LAWSUIT FOR "ALL BUTTER" LOAF CAKE

11.11.2021
Legal Bites

PROFESSIONALS

Catherine A. Veeneman

PRACTICE AREAS

Food, Beverage and Hospitality

A federal judge in the Southern District of New York dismissed a fraud and misrepresentation action against Bimbo Bakeries USA, Inc., a food company whose brands include Sara Lee, Brownberry, and Entenmann's. Plaintiff Monica Boswell brought an action against Bimbo, alleging that the company violated several New York consumer protection statutes by fraudulently advertising one of its products as an "All Butter Loaf Cake" when, in reality, the cake includes other ingredients in addition to butter, such as soybean oil and artificial flavors.

Bimbo filed a motion to dismiss Plaintiff's First Amended Complaint earlier this year, arguing that "All Butter Loaf Cake" is a fair representation of the product. The District Court agreed with Bimbo, determining that a reasonable consumer would not be misled by the phrase "All Butter" in the label. As part of its analysis, the Court recognized that the question of whether a reasonable consumer would be misled by a label depends in part upon whether the label itself is ambiguous or unambiguous. As the Court notes, when a label is unambiguous, a reasonable consumer is typically able to rely on the representations made by the label without looking at additional details provided on the packaging as any additional, less prominent, details would not cure any deception created by the primary label. When the meaning of a label is ambiguous, though, a reasonable consumer is expected to do a bit more investigating to resolve the ambiguity, namely reading through the additional information provided on the packaging, including the ingredient panel.

Here, the court determined that the label at issue, "All Butter Loaf Cake," was itself ambiguous for a few reasons. First, a reasonable consumer would know that the phrase's literal meaning-that the loaf cake is in fact "all butter"- would in all likelihood be impossible as most know that loaf cakes tend to include ingredients other than just butter. Similarly, the Court found that the label is susceptible to more than one interpretation, another indication that it is ambiguous. Because the label itself is ambiguous, the Court reasoned that a reasonable consumer would investigate the other information provided on the packaging, including the ingredient panel, where the reasonable

consumer would necessarily see that the product included other ingredients in addition to butter. As a result, the Court determined the phrase "All Butter" was not misleading in this context and granted Motion to Dismiss. Further, as the Court determined that the issue with the complaint was substantive, the Court dismissed the complaint with prejudice, denying Plaintiff a third chance at curing the defects of the Complaint.

This ruling is another indication of courts' growing fatigue and waning patience with the plethora of misrepresentation cases currently clogging the judicial system. The ruling is further encouraging for companies as it seems to endorse the idea that consumers will often not be able to rely upon just the front of a product's packaging when any ambiguity exists.

FDA ISSUES NEW SODIUM GUIDELINES

10.15.2021
Legal Bites

On October 13, 2021, the U.S. Food and Drug Administration ("FDA") released new voluntary guidance aimed at reducing average daily sodium intake by 12 percent over the next 2.5 years. The guidance sets voluntary target mean sodium concentrations and upper bound sodium concentrations for 163 food categories, including prepared foods, cheeses, sauces, frozen meals and baby food.

The FDA stated that the guidance "is intended to provide measurable voluntary short-term (2.5-year) goals for sodium content in commercially processed, packaged and prepared foods to reduce excess population sodium intake, while recognizing and supporting the important roles sodium plays in food technology and food safety." The guidance is fully voluntary and non-binding, so its effect remains to be seen.

The guidance notes that it "reflects the broad consensus among experts regarding the direct relationship between sodium and blood pressure, as well as the relationship between blood pressure and cardiovascular disease events (Ref. 4). With average sodium intake in the U.S. over 3,400 mg/day, there is considerable work to do to reduce intake to the recommended limit of 2,300 mg/day in order to reduce the risk of hypertension and cardiovascular disease. Thus, the overall goal of this guidance is to support reduction of average sodium intake to 3,000 mg/day as we continue the dialogue on sodium reduction."

PROFESSIONALS

Pooja S. Nair

PRACTICE AREAS

Food, Beverage and Hospitality

TRADER JOE'S DODGES STICKY SITUATION WITH DISMISSAL OF MANUKA HONEY FALSE ADVERTISING LAWSUIT

07.29.2021
Legal Bites

PROFESSIONALS

Catherine A. Veeneman

PRACTICE AREAS

Food, Beverage and Hospitality

The Ninth Circuit last month upheld a trial court's decision to dismiss a false advertising lawsuit against Trader Joe's concerning the store's labeling of its Manuka honey. The case, *Moore et al. v. Trader Joe's Co.*, Case No. 19-16618 (9th Cir.), centered around allegations that Trader Joe's violated multiple states' consumer protection laws by falsely labeling its Manuka honey as "100% New Zealand Manuka Honey" when, in reality, only about 57-62% of the honey is derived from Manuka nectar.

Manuka honey is created by bees that forage from the Manuka bush, a plant that is native to Australia and New Zealand. As Manuka honey contains methylglyoxal, an organic compound believed to have antibacterial properties and notable health benefits, and is in high demand, Manuka honey often sells at a price far greater than other honeys.

In its decision, the Ninth Circuit found that Trader Joe's Manuka honey label was proper as the label adhered to the requirements of the FDA's "honey guidelines" laid out in the FDCA. The FDA previously determined that a honey product may be labeled with the name of a plant or blossom if that plant or blossom is the chief floral source of the honey. Given that the FDA has not strictly defined what constitutes a "chief floral source," the Court here defined the term as meaning that the principal source of the honey came from a single source. As Trader Joe's Manuka honey is 57-62% derived from the Manuka plant, the Court determined that the honey's chief floral source was in fact the Manuka plant, meaning that Trader Joe's could accurately classify its honey as Manuka honey.

The Court went on to find that the "100% New Zealand Manuka Honey" label would not confuse a reasonable consumer into believing the honey was 100% derived from the Manuka plant as a number of contextual inferences indicate otherwise. Notable here is the fact that the Court, acknowledging that Manuka honey is a fairly niche product, considered the label from the perspective of a reasonable consumer *of Manuka honey*, rather than just a generic reasonable

consumer. The Court reasoned that anyone who actively sought out Manuka honey would have the knowledge to notice a number of contextual inferences from Trader Joe's label to determine that the "100%" claim did not mean the honey was 100% derived from the Manuka plant. Specifically, the court determined that a reasonable Manuka honey consumer would not be misled by the label as the consumer would know that:

1. It is impossible to make a honey derived from one floral source as bees naturally forage from multiple floral sources when making honey and humans cannot control this behavior;
2. Trader Joe's Manuka honey is far too inexpensive to be anywhere close to 100% from the Manuka plant. A reasonable consumer would know that a jar of honey procured close to 100% from the Manuka plant would run the consumer hundreds of dollars. Trader Joe's, on the other hand, is selling its honey for $13.99 a jar; and
3. Finally, Trader Joe's label clearly lists the honey's rating on the Unique Manuka Factor scale, indicating to a reasonable Manuka honey consumer that the honey was not 100% derived from the Manuka plant.

The Court's adoption of a reasonable consumer standard specific to Manuka honey is further confirmation that Courts will not always accept false advertising lawsuits that try to take advantage of niche products whose specific properties may not be known to a generic reasonable consumer. At least in the Ninth Circuit, courts understand and accept the proposition that niche products attract niche reasonable consumers.

HOUSE APPROPRIATIONS COMMITTEE DIRECTS FDA F&B PRIORITIES

07.15.2021
Legal Bites

PROFESSIONALS

Pooja S. Nair

PRACTICE AREAS

Food, Beverage and Hospitality

On June 30, 2021, the House Committee on Appropriations (the "Committee") issued a report accompanying a bill making appropriations for the U.S. Department of Agriculture, Food and Drug Administration ("FDA"), and related agencies for fiscal year 2022.

The report includes the Committee's review and direction as to the FDA's work. While most of this guidance was focused on drug-related regulation, the Committee offered some specific directives on food and beverage regulation that may guide the FDA's future work. The topics of interest in the report related to the food and beverage industry are included below. The Committee's guidance and direction to the FDA on these topics is likely to impact the direction of the agency and be reflected in future rulemaking and regulations in the following year.

Guidance Regarding General Food and Beverage FDA Regulation and Labeling

- "Food Additives – The Commissioner should provide a report within one year of enactment on options to systematically reassess the safety of food additives and Generally Recognized as Safe substances including how to 1) set priorities for review; 2) obtain the information on use; and 3) update its safety assessment methods to more effectively utilize modern scientific tools to evaluate the toxicity of and exposure to substances added to foods. The report should include resource needs including staffing dedicated exclusively to performing reassessment."

- "Plant-Based Product Labeling – The Committee is aware of the ongoing debate around plant-based product labels and the use of traditional meat, dairy and egg terminology. However, the Committee is concerned by the assertions being made that labeling of these products are misleading, deceptive and confusing to consumers. The Committee directs FDA to provide clarity around the labeling of plant-based foods that use traditional meat, dairy and egg terminology."

- "Dietary Supplements – The Committee is concerned with the lack of robust regulation of dietary supplements, some of which cause an estimated 23,000 emergency room visits per year that include life-threatening illnesses and deaths, and encourages the FDA to issue regulations requiring mandatory product listing and registration to create transparency in the supply chain."

- "Front of Package Labeling – The Committee is concerned with elevated rates of diet-related disease and encourages the FDA to explore issuing regulations requiring mandatory labeling to appear on the front of package for food products, allowing consumers to quickly assess the healthfulness of foods."

- "Standard of Identity Activities for Foods – The Committee is concerned with the lack of transparency and progress in modernizing the FDA's standards of identity regulations. To fulfill the Committee's previous instructions, not later than 30 days after the date of enactment of this Act, and annually thereafter, the FDA shall submit to the Committees, and make publicly available online, a report outlining its progress on modernizing its standards of identity regulations, including demonstration of improved transparency and improved progress."

- "Traceback – The Committee recognizes that the ability to trace back contaminated products is critical to containing food safety outbreaks but that challenges associated with tracing these products from the end-consumer through the supply chain continue to persist. The Committee directs FDA to emphasize in its final rulemaking the importance of capturing at the point of sale details such as the lot number and product identifier instead of prescribing the mechanism by which the information is shared through the supply chain. The Committee also directs FDA to ensure these details are maintained from the point of origination, creation, and/or transformation through to the retail food or food service establishment. To avoid duplication, the Committee urges FDA to clearly define traceability requirements that, where possible, align with existing consensus standards for traceability utilized by industry and allow for records to be maintained in electronic and paper form."

- "Food Traceability – The Committee provides an increase of $9,500,000 to facilitate traceability and enhance outbreak response to prevent further illnesses. The Committee is encouraged by the work FDA has done in developing a blueprint to outline strategies to develop a wide-scale traceability system that helps companies and government agencies more rapidly trace foods implicated in disease outbreaks and subject to recall through their New Era of Smarter Food Safety Initiative."

- "PFAS in Food – FDA should continue its work to investigate PFAS in our national diet and in food packaging that contacts food."

- "Net Weights – The Committee encourages FDA to continue devoting appropriate efforts to address suspected economic integrity issues, particularly with respect to net weights, and treatment of seafood. The Committee believes ''short-weighted'' labeled products are violating FDA laws and that, despite industry reporting such examples, FDA has not prioritized enforcement. The Committee requests an update from FDA on its efforts to enforce net weight requirements with respect to seafood products."

Guidance Regarding Specific Categories of Food and Beverage Products

- "Dairy Standard of Identity – The Committee is pleased that the FDA has begun a deliberative process to review how it will enforce the standards of identity for dairy products as described in 21 Code of Federal Regulations parts 131, 133 and 135. The Committee continues to hear concerns with the labeling of certain foods and beverages as dairy products when the products are plant-based rather than derived from an animal. As such, the Committee urges the FDA to continue its work toward ultimately enforcing standards of identity for dairy products."

- "Gluten – The Committee is aware that celiac disease is a serious, genetic autoimmune disorder, affecting nearly 3 million Americans, in which ingesting gluten causes damage to the villi of the small intestine. The only treatment is the total elimination of gluten-containing products. In 2017, FDA issued Draft Guidance encouraging drug manufacturers to disclose the presence of gluten. While some manufacturers have taken this step, it has not been implemented consistently. This may lead consumers to face continued uncertainty about whether their medicine will do more harm than good. The Committee continues to encourage FDA to consider docket comments received from stakeholders, including consumers, and to work expeditiously to publish a final guidance document."

- "Seafood Product Labeling – The Committee notes that certain foods are labeled as a fish or seafood product when the products are highly processed plant-based foods rather than derived from actual fish or seafood. The Committee directs the FDA to continue to assess products on the market to determine whether action is necessary to ensure consumers are not misled regarding such product labeling."

- "Sesame – The committee is concerned that the recent FDA Draft Guidance for Industry on Voluntary Disclosure of Sesame is insufficient to protect Americans with sesame allergy and directs FDA to consider further action to require sesame to be labeled the same as other major allergens."

- "Canned Tuna – The Committee remains concerned that FDA has not revised the standard of identity for canned tuna to adopt the drained weight fill of container standard despite having received two citizens petitions, as far back as 1994. FDA is directed to promulgate proposed regulations revising the standard of identity for canned tuna consistent with the drained weight standard adopted for canned tuna by the Codex Alimentarius Commission and the Association of Official Analytical Chemists canned tuna, FDA shall, to the extent consistent with applicable regulations, continue to approve in a timely manner temporary marketing permits that adopt the drained weight method consistent with international standards and to approve in a timely manner updates to product labeling under existing temporary marketing permits."

- "Botanical Dietary Supplements Quality and Safety – The Committee encourages the continued work between the National Center for Natural Products Research and the FDA to conduct research on biological and chemical properties of plants used in dietary supplements, in order to ensure the quality and safety of these products. This collaborative effort helps develop the science base for ensuring the authenticity, quality and safety of botanicals sold as dietary supplements in the U.S."

- "Olive Oil Standards of Identity – The Committee is aware that the United States continues to be an important producer of olive oils and one of the largest olive oil markets globally. Accordingly, the Committee believes that the establishment of a uniform set of standards would better protect and inform consumers, and directs the FDA to continue to explore a Standard of Identity for different grades of olive oil as required in H. Rpt. 116–446 and provide an updated report to the Committees no later than December 31, 2021."

FDA Foods Program Releases Guidance Topics

07.09.2021
Legal Bites

Professionals

Pooja S. Nair

Practice Areas

Food, Beverage and Hospitality

On June 29, 2021, the U.S. Food and Drug Administration's ("FDA") Center for Food Safety and Applied Nutrition and Office of Food Policy and Response released a list of draft and final guidance topics that are a priority for the FDA Foods Program to complete during the next 12 months.

The FDA anticipates publishing guidance for many of these documents by June 2022. The FDA stated that the agency "is taking this action to provide stakeholders increased transparency and additional insights into the foods program priorities. Guidance documents represent the FDA's current thinking on a specific topic and the information can help stakeholders plan for potential changes that may impact their businesses and organizations. They do not impose legally enforceable requirements."

The FDA further stated that in the future the agency "intends to release the list of anticipated human food and cosmetic guidance topics at the beginning of each calendar year with updates scheduled for mid-year." The list released on June 29 will be updated by the end of January 2022.

The guidance topics announced include:

- Evaluating the public health importance of food allergens other than the major food allergens
- Questions and answers regarding food allergens
- Policy regarding certain new dietary ingredients and dietary supplements subject to the requirement for pre-market notifications
- Best practices for convening a GRAS panel
- Action levels for lead in juice
- Lead action levels for categories of foods consumed by babies and young children
- Prevention of salmonella enteritidis in shell eggs during production
- Reducing microbial food safety hazards in the production of seed for Sprouting

- Labeling of plant-based milk alternatives
- Voluntary sodium reduction goals: target mean and upper bound concentrations for sodium in commercially processed, packaged and prepared foods

Public comments on the guidance can be submitted to www.regulations.gov.

NINTH CIRCUIT REJECTS PROPOSED FALSE ADVERTISING SETTLEMENT AGREEMENT SEEKING DISPROPORTIONATE ATTORNEYS'

06.22.2021
Legal Bites

PROFESSIONALS

Catherine A. Veeneman

PRACTICE AREAS

Food, Beverage and Hospitality

Earlier this month, the Ninth Circuit reversed approval of a class action settlement, finding several indications that the proposed settlement was the result of collusion between the parties and did not adequately serve the class. The case, *Briseño et al. v. ConAgra Foods Inc.*, Case No. 19-56297 (9th Cir.), originally filed in 2011, centers around allegations that defendant ConAgra Food Inc., then-owner of Wesson Oil, falsely advertised its oil as "100% Natural" when in fact the oil contained ingredients made from GMOs.

After several years of litigation, plaintiffs successfully had a class certified under Federal Rule of Civil Procedure 23(b)(3). In November 2018, the parties reached a post-certification settlement. The parties agreed to both monetary and injunctive relief for the class. Specifically, the agreement provided that (1) each class member would receive $0.15 for each unit purchased; and (2) ConAgra would not market or advertise Wesson Oil as "natural" anymore (an easy feat, considering ConAgra had at that point already sold Wesson Oil to a separate third party). The settlement agreement also had a provision that Plaintiff would request, and ConAgra would not contest, $6.85 million in attorneys' fees and expenses. Notably, attorneys' fees would come directly from ConAgra, as opposed to from the class fund. As a result, any reduction to the fee by the court would benefit ConAgra, not the class.

Payments to the class members would be disbursed on a claims-made basis, however ConAgra did not have an obligation to send out direct notice to class members. Of the 15 million class members, only about .5% submitted a claim. As a result, the class would earn in total less than $1,000,000.

One class member objected to the settlement on the grounds that, under the revised FRCP 23(e), the settlement was the result of collusion as class counsel ended up with roughly 88% of ConAgra's payout in attorneys' fees. The district court rejected the objector's arguments, finding the settlement sufficiently fair. The objector appealed this decision to the Ninth Circuit. The appellate court, in a published opinion, reversed the district court's approval of the

settlement agreement, finding that the district court erred by failing to apply the new FRCP Rule 23(e)(2) standard, which requires scrutiny of the attorney fee arrangement when analyzing a settlement agreement for fairness.

As the Ninth Circuit notes, under the new Rule 23(e)(2), one factor the court must consider when assessing a proposed settlement is "the terms of any proposed award of attorney's fees[.]" To properly assess this factor, a court must apply the heightened scrutiny established in *In re Bluetooth Headset Products Liability Litigation*, 654 F.3d 935 (9th Cir. 2011) to determine whether the division of funds between class members and class counsel was in fact fair. Specifically, *In re Bluetooth* sets up three facts that must be considered:

1. Whether class counsel received a disproportionate distribution of the settlement;
2. The existence of a "clear sailing arrangement" (a provision that states the defendant will not challenge class counsel's fee request); and
3. Whether the agreement had a "kicker" or "reverter" clause in which the defendant, rather than the class, would receive the remaining funds if the court reduced the agreed-upon attorneys' fee amount.

Here, the appellate court found all three *Bluetooth* factors present. Notably, class counsel would receive nearly $7 million in attorneys' fees, whereas the class would receive less than $1 million. Further, the proposed agreement contained both a clear sailing provision in which ConAgra agreed to not contest class counsel's request for fees, as well as a reverter clause that held that any fees not awarded to class counsel would revert back to ConAgra as opposed to the class. The Ninth Circuit therefore reversed the district court's approval of the settlement and remanded for further proceedings.

The Ninth Circuit's decision confirms that courts will continue to closely evaluate the attorneys' fees rewarded in a case when determining the fairness of a class action settlement. Further, the opinion confirms that the heightened level of scrutiny established in *In re Bluetooth* and solidified in the revised FRCP 23(e)(2) will apply to post-class certification settlement agreements as well as pre-certification agreements.

FDA ISSUES FINAL RULE ON YOGURT STANDARD OF IDENTITY

06.16.2021
Legal Bites

PROFESSIONALS

Pooja S. Nair

PRACTICE AREAS

Food, Beverage and Hospitality

On June 11, 2021, the FDA issued a final rule to amend the standard of identity for yogurt. The rule will become effective on July 12, 2021.

A standard of identity describes in detail what a food product must contain, how it must be proportioned and in some cases how it must be manufactured. The FDA has more than 280 standards for a wide variety of food products. As part of the FDA's Nutrition Innovation Strategy, the agency has been considering standards of identity and particularly looking to revoke or update standards when they are inconsistent with modern manufacturing processes or create barriers to innovation.

Prior to the final rule, the FDA had set three different standards of identity for yogurt, low-fat yogurt and nonfat yogurt. Under the final rule, the standards of identity for low-fat yogurt and nonfat yogurt are revoked and all three products fall under one more flexible standard of identity.

The FDA stated that its action was, in part, a response to a citizen petition submitted by the National Yogurt Association in February of 2000. That petition requested that the FDA revoke the standards of identity for low-fat yogurt and nonfat yogurt and amend the standard of identity for yogurt.

The FDA stated that the intent of the rule was to modernize the yogurt standard to "allow for technological advances while preserving the basic nature and essential characteristics of yogurt" and promoting honesty and fair dealing for consumers.

The FDA constituent update on the rule states: "The final rule expands the allowable ingredients in yogurt, including sweeteners such as agave, and reconstituted forms of basic dairy ingredients. It establishes a minimum amount of live and active cultures yogurt must contain to bear the optional labeling statement "contains live and active cultures" or similar statement. For yogurt treated to inactivate viable microorganisms, the statement "does not contain live and active cultures" is required on the label. Additionally, the final rule supports the many innovations that have already been made in the

yogurt marketplace, including continuing to allow manufacturers to fortify yogurts, such as adding vitamins A and D, as long as they meet fortification requirements. The rule also allows various styles or textures of yogurt as long as they meet requirements in the standard of identity."

The agency is accepting objections and requests for a hearing until July 12, 2021.

The compliance date of this final rule is January 1, 2024, which has been set as the uniform compliance date for all final food labeling regulations issued in 2021 and 2022.

FDA Announces $134M Budget Increase for FY 2022

06.09.2021
Legal Bites

On June 7, 2021, the FDA released its Fiscal Year 2022 budget request, outlining key investments for food safety. The request details how the FDA plans to use funds in FY 2022 to support food safety and nutrition. The budget provides increases to core food safety programs and outlines emerging issues of concern for the agency.

The agency's FY 2022 Budget provides $1.6 billion in budget authority for food safety, an increase of $134 million from the previous year.

The agency's press release states: "[o]f the increase of $134 million for food safety activities, $45 million is for efforts to support initiatives to advance the New Era of Smarter Food Safety, including $23 million for food safety requested as part of FDA's Data Modernization and Enhanced Technologies initiative. The New Era initiative, announced in 2019, strives to leverage new technologies and approaches to create a more digital, traceable and safer food system.

The budget also supports critical food safety initiatives that include $20 million for Emerging Chemical and Toxicology Issues and $18 million for Maternal and Infant Health and Nutrition.

Additional funding will support the agency in keeping pace with the latest advances in science and technology and addressing issues of concern, such as maternal and infant health and nutrition and emerging chemical and toxicology issues. Likewise, without new resources for the New Era of Smarter Food Safety, the FDA's ability to maintain the safeguards needed to help keep foods safe will significantly lag behind rapid, sweeping changes in the marketplace, potentially putting consumers at risk."

Professionals

Pooja S. Nair

Practice Areas

Food, Beverage and Hospitality

FDA ANNOUNCES INTENDED CONSUMER RESEARCH ON "HEALTHY" CLAIMS

05.26.2021
Legal Bites

PROFESSIONALS

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PRACTICE AREAS

Food, Beverage and Hospitality

On May 6, 2021, the FDA issued a procedural notice on the preliminary quantitative consumer research it plans to conduct on symbols that could be used in the future to convey the nutrient content claim "healthy."

This research is part of the FDA's Nutrition Innovation Strategy, which seeks to reduce the burden of nutrition-related chronic diseases and to modernize claims. By using a symbol for a nutrient claim, the goal would be for consumers to have a quick signal about what benefits a food or beverage they choose might have.

As part of its efforts to promote public health, FDA proposes to conduct three consecutive quantitative research studies–an experimental study and two surveys–to explore consumer responses to the draft front-of-package ("FOP") symbols that manufacturers could voluntarily use on a food product as a graphic representation of the nutrient content claim "healthy."

The FDA is inviting public comment on the following issues: "(1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology." Comments can be submitted here.