



LEGISLATION, REGULATIONS & STANDARDS

## Omnibus Spending Bill Includes Congressional Notes to FDA

President Biden has signed a spending bill that includes additional funding for the U.S. Food and Drug Administration (FDA) along with several notes in the Senate Committee on Appropriations' [explanatory statement](#) detailing concerns expressed by the lawmakers. Issues addressed include the [Reagan-Udall Foundation's December 2022 report](#) on the culture of the agency.

“The food program's recent missteps and delayed actions outlined in the Reagan-Udall Foundation report have revealed the serious consequences of FDA continuing to operate with a fragmented organizational structure and lack of accountability. To better regulate food and improve the food program, the agreement encourages the FDA to strongly consider the report's recommendations and develop a restructuring plan, that includes stakeholder engagement and input, that establishes and unifies all capacities of the food program.”

The committee's statement also addressed food inspections. “The agreement is concerned that human food facilities are not inspected frequently enough to adequately identify and respond to risks. The FDA is directed to increase the frequency of domestic human food inspections and develop a report for the Committees that identifies operational changes and determine the resource implications of conducting inspections every 18 months for high-risk domestic facilities and every three years for non-high-risk domestic facilities.”

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The statement further directs FDA to establish a standard of identity for different grades of olive oil and notes concern “about the proliferation of products marketed using standards of identity for dairy products that do not contain dairy ingredients. The agreement directs the FDA to implement an updated enforcement approach to enforce against dairy imitation products.” In addition, the committee urged FDA to “promptly consider any application for a Temporary Marketing Permit” following the issuance of the final rule for yogurt’s standard of identity.

The committee also noted added sugar labeling: “The agreement remains concerned about potential consumer confusion over nutritional labeling requirements and guidelines for added sugar, for products such as honey and maple syrup. The agreement directs the FDA to continue working with impacted industries to ensure clear and appropriate labeling.”

## FDA Approves Changes to Yogurt Standard of Identity

After receiving objections from a dairy industry group and yogurt maker Chobani, Inc., the U.S. Food and Drug Administration (FDA) announced in December it has modified a final rule amending the definition and standard of identity for yogurt.

In June 2021, FDA initially issued a final rule in response to a citizen petition from the National Yogurt Association. The final rule revoked the standards of identity for lowfat and nonfat yogurt. The final rule expanded to allow for more ingredients in yogurt, including sweeteners like agave, and reconstituted forms of dairy ingredients. It also established a minimum amount of live and active cultures for yogurt to include an optional labeling statement “contains live and active cultures.”

In response to the final rule, the International Dairy Foods Association (IDFA) and Chobani filed objections and sought hearings on several provisions of the final rule.

FDA agreed to modify provisions to allow the use of all safe and suitable sweeteners, including non-nutritive sweeteners, and to make the minimum optional fortification of Vitamin D 10% of the Daily Value, consistent with the agency’s food additive regulations. The agency also modified the general definition and standard of identity under 21 CFR 130.10 to permit the use of fat-containing flavors (including coconut flakes and chocolate) in lower fat yogurt.

The rule takes effect January 17, 2023, and the compliance date is January 1, 2024.



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### ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.



# Adulterated Honey Prompts FDA Import Alert



An effort from the U.S. Food and Drug Administration (FDA) to test imported honey for undeclared added sweeteners found that 10% of tested samples were adulterated, according to recently released FDA [data](#).

In 2021 and 2022, FDA carried out a sampling assignment testing imported honey for economically motivated adulteration (EMA). EMA occurs when someone intentionally leaves out, takes out or substitutes a valuable ingredient or part of a food, or when a substance is added to food, to make it appear better or to be of greater value.

FDA tested 144 imported honey samples from bulk and retail shipments from 32 countries for the presence of less expensive undeclared added sweeteners. Of those, 14 samples were violative. FDA refused entry of the violative shipments into the United States and placed the associated company and product on an import alert.

"The FDA routinely assesses imported honey products to ensure accurate product labeling and otherwise help keep consumers from being deceived," the agency said in a constituent update. "The agency will continue to test honey for EMA under the agency's import sampling and risk-based import entry screening program."

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## LITIGATION

### Grillo's Sues Wahlburgers for Preservative Claims

Pickle maker Grillo's Pickles, Inc. has filed suit against the maker of Wahlburgers pickles, alleging the company makes misleading claims about its pickles' freshness and all natural and preservative-free status. *Grillo's Pickles, Inc. v. Patriot Pickle Inc.*, No. 23-00011 (D.N.J., filed January 3, 2023).

Grillo's said in its complaint that Wahlburgers pickles are sold nationally and marketed as "fresh," "all natural," and containing "no preservatives," while the pickles "contain considerable amounts of an artificial preservative designed to lengthen the pickles' shelf life."

Grillo's asserts that Wahlburgers pickles are formulated to taste nearly identical to their pickles, and that Wahlburgers' pickles' "false and misleading statements are the keys which have allowed Wahlburgers pickles to access and compete with Grillo's in the fresh, artificial-preserved-free pickle market."

"Absent these false and misleading statements, Wahlburgers pickles would not have been in the same fresh, artificial-preserved-free category as Grillo's pickles and would not have been purchased by consumers to whom these attributes are important," the plaintiff said in the complaint. "Further, absent these false and misleading statements, Wahlburgers pickles would not have been viewed by grocery stores and consumers as a substitute product for Grillo's and would not have been purchased by customers and grocery store buyers to the detriment of Grillo's sales, allotted shelf space, and market share."

Grillo's also noted similarities in product containers between the two companies, furthering the impression that Wahlburgers pickles are interchangeable with their own. Grillo's is alleging false advertising under the Lanham Act and unfair competition. The company is seeking declarative and injunctive relief, defendants' profits, treble damages, reasonable attorneys' fees and punitive damages.

## Illinois Court Dismisses Target Water Enhancer Lawsuit

An Illinois federal court has granted Target Corp.'s motion to dismiss a putative class action alleging Market Pantry concentrated liquid water enhancers contain an artificial form of malic acid despite the product's "natural flavoring" label representation. *Gouwens v. Target Corp.*, No. 22-50016 (N.D. Ill., W. Div., entered December 30, 2022).

The court dismissed the allegations brought under the Illinois Consumer Fraud and Deceptive Business Practices Act, finding that the plaintiff's claim "is based on a fanciful and unreasonable interpretation of the Product's label." Target argued that "it is not misleading for it to 'disclose that its products contain natural flavors or to use an accurate regulatory disclosure that is mandated by federal law,'" and the court agreed. Then, finding that the common law claims of breach of express warranty and fraud required "a plausible allegation of deception," which the plaintiff lacked, the court dismissed those claims as well.

## AriZona Beverages Sued for All Natural, Preservative-Free Claims

A California man is suing beverage maker AriZona Beverages USA, LLC, alleging it falsely labels and advertises its products as being “all natural” when they contain artificial ingredients and preservatives. *Iglesias v. Arizona Beverages USA, LLC*, No. 22-9108 (N.D. Cal., December 23, 2022).

The suit identifies several products, including AriZona juice cocktails, teas, lemonades and drink mixes. The plaintiff alleges the products include labeling touting them as “All Natural,” “100% Natural” or “100% All Natural” but contain ingredients such as added coloring, ascorbic acid, high fructose corn syrup, malic acid, erythritol and natural flavors. The plaintiff also asserted the company misleads consumers with labeling that the products contain “No Preservatives.”

In his complaint, the plaintiff said consumers are willing to pay more for all natural and preservative-free products and asserted that AriZona Beverages seeks to capitalize on that preference.

“Defendant’s practice of capitalizing on consumers’ preferences for healthier products is deceptive,” he alleged. “This deception continues today, as consumers continue to purchase the Products under the mistaken belief that they are all natural and preservative-free based on Defendant’s false, deceptive, and misleading label claims of ‘All Natural,’ ‘100% Natural,’ ‘100% All Natural,’ and ‘No Preservatives.’”

For alleged violations of the California Consumers Legal Remedies Act, the California False Advertising Law and California Unfair Competition Law, as well as unjust enrichment and breach of express warranty, the plaintiff is seeking class certification, declaratory judgment, injunctive relief, damages, pre- and post-judgment interest and attorney’s fees.

## Florida Consumer Sues Schwan's for Pies' 'No Preservatives' Claims

A Florida woman has filed suit against Schwan's Consumer Brands Inc., alleging the labeling of the company's Edwards pies as having “No Preservatives” is misleading. *Martin v. Schwan's Consumer Brands Inc.*, No. 22-469 (N.D. Fla., December 31, 2022).

The suit is focused on Edwards' key lime pie and strawberry crème pie products, which both include the same “No Preservatives” representation on the front of the products’

packaging. The plaintiff said the representation is false and misleading because the pies contain sodium citrate and citric acid.

The plaintiff said not only do the labels not disclose a chemical preservative that acts as a preservative as required by law, “they do the opposite by disclaiming the presence of preservatives.”

“Federal and identical state law require the Product to disclose that it contains the chemical preservatives of citric acid and sodium citrate, in a manner that such statements are likely to be read by the ordinary person under customary conditions of purchase and use of the Product,” she said in the complaint. “By not disclosing the use of chemical preservatives, and further asserting the Product contains ‘No Preservatives,’ Defendant misleads reasonable consumers.”

For alleged violations of the Florida Deceptive and Unfair Trade Practices Act and other state consumer fraud acts, breach of express and implied warranty, negligent misrepresentation, fraud and unjust enrichment, the plaintiff is seeking class certification, injunctive relief, damages and costs, including attorney’s fees.

## Capri Sun Preservative Claim Prompts Consumer Suit

A New York woman has filed a proposed class action against Kraft Heinz Foods Co. alleging its Capri Sun apple juice misleads consumers as to its preservative content. *Forbes v. Kraft Heinz Food Co.*, No. 23-0007 (S.D.N.Y., filed January 2, 2023).

The plaintiff alleges that the statement “No Artificial Colors, Flavors or Preservatives” on the product’s packaging is misleading because the product contains citric acid, an artificial ingredient which serves multiple preservation functions. Additionally, she asserted that the defendant’s use of the parenthetical declaration “FOR TARTNESS” next to citric acid on the ingredient list “is misleading and contrary to law.”

“While the relevant regulation allows the description of a preservative to reference its effect on flavor, a consumer who even views the ingredient list will not know that the ‘tartness’ is provided to maintain and restore the Product’s taste,” she said. “They will just think the citric acid impacts the Product’s flavor, which is true, but also misleading because it fails to disclose it requires this ingredient to maintain, preserve and protect its flavor from deteriorating.”

For alleged violations of the New York General Business Law, other state consumer fraud acts, breaches of express and implied

warranty, fraud and unjust enrichment, the plaintiff is seeking class certification, damages and costs, including attorney's fees.

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