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FOOD AND BEVERAGE LITIGATION AND REGULATORY UPDATE

SHOOK HARDY & BACON

LEGISLATION, REGULATIONS & STANDARDS

FDA Announces Update on Human Foods Program Restructuring

The U.S. Food and Drug Administration (FDA) has issued a news release with an update on the restructuring of its Human Foods Program and Office of Regulatory Affairs (ORA). "I cannot stress enough that my vision is focused on a new, agency-wide model where the activities and responsibilities of the regulatory programs and ORA are better synced to improve efficiency and effectiveness with clear decision rights so that everyone knows who has authority," Commissioner Robert Califf said in the press release, which also indicates that the agency has begun searching for a candidate to fill the role of deputy commissioner for human foods.

FDA announced that it has begun assessing existing processes and functions with the aim to finalize the restructuring proposal in fall 2023, which will include "the newly designed structure, an established budget, and a detailed mapping and crosswalk of staff from the current to new organization."

FDA Withdraws Proposed Food Standards Modernization Rule

The U.S. Food and Drug Administration (FDA) is withdrawing its 2005 proposed rule "Food Standards; General Principles and Food Standards Modernization" in response to comments the agency received after it published the rule in 2005 and after it reopened the comments period in 2020.

M. Katie Gates Calderon
816.559.2419
kgcalderon@shb.com

The rule, which FDA jointly published with the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), was intended to establish a set of general principles for FDA and FSIS to use when considering whether to establish, revise or eliminate a food standard.

FDA reopened the comment period in February 2020 in response to stakeholder feedback that FDA should solicit new data and information when determining next steps for the proposed rule to reflect changes in manufacturing, food technology, market trends and nutrition since 2005.

"Many of the comments submitted suggested that the general principles be revised and consolidated to make the principles easier to understand and implement," FDA said in a constituent update. "The FDA and USDA-FSIS agree and are withdrawing the proposed rule to reconsider how best to approach general principles and food standards modernization to ensure any future revised general principles are consistent with the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act."

Lindsey Heinz
816.559.2681
lheinz@shb.com

James P. Muehlberger
816.559.2372
jmuehlberger@shb.com

LITIGATION

Consumer Brings Lead Claims Against Maker of Hu's Organic Dark Chocolate

A New York consumer has filed a proposed class action against the maker of Hu's brand dark chocolate, alleging it failed to disclose that the products contain unsafe levels of lead. *Levy v. Hu Products LLC*, No. 23-1381 (S.D.N.Y., filed February 17, 2023).

The product at issue is Hu's Organic Simple Dark Chocolate 70% Cocoa chocolate bars. The suit follows a December 2022 report in *Consumer Reports* that found many chocolate products contained high levels of heavy metals, including lead and cadmium. The plaintiff cites *Consumer Reports*' finding that the Hu's product contained 210% of California's maximum allowable dose level (MADL) for lead. The plaintiff asserted the defendants' advertising and marketing is deceptive because it does not disclose the high levels of lead in the products.

"The presence of lead, particularly in high or elevated levels, in food products is unquestionably material to reasonable consumers, because the chemical poses serious health risk, even in small dosages," the plaintiff said in the complaint. "In addition, the lead levels in the Products could not be known before

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.

purchasing them, and may not be determined without extensive and expensive scientific testing."

For claims of breach of implied and express warranty, violations of Sections 349 and 350 of the New York General Business Law, and unjust enrichment, the plaintiff is seeking class certification, declaratory judgment, damages, prejudgment interest, restitution and costs and fees including attorney's fees.

Consumer Alleges Gatorade Fit Drinks are Misbranded as 'Healthy'

A California consumer has filed a putative class action against PepsiCo Inc., alleging it unlawfully markets its Gatorade Fit drinks as healthy. *Gumner v. Pepsico, Inc.*, No. 23-0332 (C.D. Cal., filed February 24, 2023).

The plaintiff said in his complaint that product labeling language including "Real Healthy Hydration," "No Added Sugar" and "Excellent Source of Vitamin A & C" amounted to misbranding under the Federal Food, Drug, and Cosmetic Act and its California equivalent.

In his complaint, he said the product "is essentially water that is flavored with a small amount of watermelon juice concentrate and citric acid and sweetened with stevia leaf extract," and, absent fortification, the product would not provide 10% or more Vitamin A or C.

"By using the Misbranded Claims, Pepsi was able to gain a greater share of the relevant drink market than it would have otherwise and also increased the size of the market," he said. "Plaintiff would not have purchased Gatorade Fit if he had known that the Products were misbranded pursuant to California and federal labeling laws and regulations."

The plaintiff's claims include alleged violation of the California Unfair Competition Law and unjust enrichment. He is seeking class certification, restitution and interest; and attorney's fees and costs.

Consumers Allege GNC Deceptively Advertised Lean Bars

Two New York consumers have filed suit against GNC, alleging it had no basis to label its Total Lean products as lean because they do not contain any less fat in comparison to similar "non-lean"

protein products on the market. *Mercado v. GNC Holdings, LLC*, No. 23-1572 (S.D.N.Y., filed February 24, 2023).

The plaintiffs said in their complaint that GNC markets and sells its Lean Bars as "lean" to "impress upon the public that its products contain less fat than its competitors."

"However, the Products do not comply with 21 C.F.R. 101.62(e) and therefore do not meet such warranties," the plaintiff said. "Accordingly, Defendant has no basis to label its Products as 'lean.'"

The plaintiffs said they both purchased GNC's Lean Bars, which contain 12 grams of fat per 100 grams of product, or two grams over the statutory limit. They accuse the company of engaging in false and deceptive advertising.

The plaintiffs have alleged violations of Sections 349 and 350 of the New York General Business Law, and breach of express and implied warranties. They are seeking class certification, declaratory judgment damages, injunctive relief, prejudgment interest and costs and expenses including attorney's fees.

SCIENTIFIC / TECHNICAL ITEMS

Study Finds Potential Links Between Erythritol and Cardiovascular Risk

A new study published February 27, 2023, in the journal *Nature Medicine* has purportedly found possible links between erythritol and major adverse cardiovascular events such as heart attack or stroke. Erythritol is an artificial sweetener frequently used in "zero-calorie" and keto-friendly prepared foods and beverages.

"Following exposure to dietary erythritol, a prolonged period of potentially heightened thrombotic risk may occur," the study's authors said. "This is of concern given that the very subjects for whom artificial sweeteners are marketed (patients with diabetes, obesity, history of [cardiovascular disease (CVD)] and impaired kidney function) are those typically at higher risk for future CVD events." They said that more studies investigating the impact of erythritol specifically, as well as artificial sweeteners in general, are needed.

In response to the study, the Calorie Control Council, an industry group, issued a statement that the results of the study "are contrary to decades of scientific research showing reduced-calorie sweeteners like erythritol are safe, as evidenced by global regulatory permissions for their use in foods and beverages."

MEDIA COVERAGE

New York Times Covers Lawsuit Against Jack Daniel's Distillery

The New York Times has published an article about litigation centered on the growth of whiskey fungus in areas across Lincoln County, Tennessee, near the distillery that produces Jack Daniel's whiskey. Residents argue that the vapors of alcohol aging in barrelhouses feed the development of the fungus on nearby properties, covering trees, houses, road signs and cars in "a sooty, dark crust." A representative of Jack Daniel's reportedly said that whiskey fungus can be "a nuisance" but is not hazardous to human health and does not damage property, while a University of Toronto professor who has studied the fungus apparently told the *Times* it is "pretty destructive, and the only way to stop it is to turn off its alcohol supply." The nearby residents seek to prevent the county from allowing Jack Daniel's to build additional barrelhouses, and a court has ruled that the company must stop construction on one barrelhouse currently underway until it obtains the necessary permits.