FOOD & BEVERAGE LITIGATION UPDATE

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SHOOK HARDY & BACON

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Federal Agencies Target Dietary Supplement Manufacturers and Distributors

The U.S. Department of Justice (DOJ) and U.S. Food and Drug Administration (FDA) have announced the latest developments in civil and criminal actions taken against 117 dietary supplement manufacturers and distributors as the result of a yearlong investigation into allegedly tainted products. According to a November 17, 2015, DOJ press release, an 11-count indictment alleges that weight-loss and workout supplement manufacturer USPlabs LLC "engaged in a conspiracy to import ingredients from China using false certificates of analysis and false labeling and then lied about the source and nature of those ingredients." The indictment claims the products in question were sold to retailers across the nation, with USPlabs asserting that it used natural plant extracts "when in fact it was using a synthetic stimulant manufactured in a Chinese chemical factory."

"The joint agency effort is a testament to our commitment to protecting consumers from potentially unsafe dietary supplements and products falsely marketed as dietary supplements," said FDA Deputy Commissioner for Global Regulatory Operations and Policy Howard Sklamberg. "The criminal charges against USPlabs should serve as notice to industry that if products are a threat to public health, the FDA will exercise its full authority under the law to bring justice." *See DOJ* and *FDA Press Releases,* November 17, 2015.

FDA Determines GE Salmon Safe for Consumption, Environment

The U.S. Food and Drug Administration (FDA) has released its **determination** that genetically engineered (GE) salmon produced by AquaBounty Technologies, Inc., is as safe to eat as conventional salmon and will have little effect on the environment. Containing genes from Pacific Chinook salmon and ocean pout that accelerate growth and maturation, AquAdvantage® salmon is the first GE animal approved for human consumption.

After spending more than a decade reviewing data on food safety and environmental impacts, the agency apparently **concluded** that (i) "the inserted genes remained stable over several generations of fish," (ii) "food from the GE salmon is safe to eat by humans and animals," (iii) "the genetic engineering is safe for the fish," and (iv) "the salmon meets the sponsor's claim about faster growth." FDA also found that the multiple containment measures taken by land-based production facilities are sufficient to prevent the fish from mixing with wild populations. *See FDA News Release,* November 19, 2015.

As reported in **Issue 15** of this *Update,* AquaBounty's GE salmon first drew scrutiny from health and environmental groups as early as 2003, when the Pew Initiative on Food and Biotechnology issued a report suggesting that attempts to regulate transgenic fish as "new animal drugs" may not survive legal challenges. In the wake of FDA's announcement, consumer groups are still divided over the regulation of bioengineered animals. While the Center for Science in the Public Interest (CSPI) praised the rigorous approval process and called for transparency in marketing the fish, the Center for Food Safety (CFS) vowed to file a lawsuit against the agency. In addition, a coalition of Alaskan lawmakers dedicated to banning the sale and importation of so-called "Frankenfish" have condemned the decision as "harebrained."

"I am livid at the FDA's announcement to approve genetically engineered 'salmon'—what seems to be more science experiment than fish or food," said U.S. Sen. Lisa Murkowski (R-Alaska). "I have adamantly opposed the approval of GE salmon, both for the health of Americans and the sustainability of our fisheries, but now that the decision has been made, the next step must be to ensure that Americans know what they are consuming. I have introduced both a bill and provision in the appropriations process to mandate the labeling of Frankenfish, and it is more imperative than ever, after this potentially disastrous decision, to make sure they become law." *See CSPI Statement, CFS Press Release* and *Sen. Murkowksi Press Release,* November 19, 2015.

FDA Issues Labeling Guidance for Foods Derived from GE Plants, GE Salmon

In conjunction with its decision to approve the first genetically engineered (GE) animal for human consumption, the U.S. Food and Drug Administration (FDA) has published final labeling guidance for foods derived from GE crops and draft labeling guidance for GE salmon.

Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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Titled "**Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants**," the final guidance document seeks to assist "food and feed manufacturers that wish to voluntarily label their plant-derived food products or ingredients (for humans or for animals) as having been made with or without bioengineering." In addition, the agency's draft labeling guidance—"**Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon**"—describes the preferred labeling terms for products marketed as containing or avoiding transgenic salmon.

Emphasizing that such labeling should be "truthful and not misleading," the agency recommends that manufacturers wishing to identify their products as *not* derived from GE ingredients use phrases such as "not bioengineered" or "not genetically modified through the use of modern biotechnology," as opposed to "GMO free," "GE free," "does not contain GMOs," "non-GMO," or similar claims. In particular, the labeling guidance pertaining to GE-derived plant ingredients advises manufacturers that the term "free" is not only difficult to substantiate, but the acronym "GMO" may confuse consumers because "most foods do not contain entire organisms."

"However, FDA does not intend to take enforcement action against a label using the acronym 'GMO' in a statement indicating that the product (or an ingredient) was not produced through the use of modern biotechnology, as long as the food is, in fact, not derived from a genetically engineered plant and the food's labeling is not otherwise false or misleading, as further discussed in this guidance," notes FDA. "Similarly, we do not intend to take enforcement action against a label using the acronym 'GMO' in a statement indicating that the product (or an ingredient) was produced through the use of modern biotechnology, as long as the statement was true and the food's labeling is not otherwise false or misleading."

Both guidance documents also address the substantiation of GE ingredient claims, including, where appropriate, (i) "the documentation of handling practices and procedures", (ii) "the use of certified organic food," and (iii) "the use of validated test methods." FDA will accept comments on the draft labeling guidance for foods derived from GE salmon beginning November 23, 2015.

FDA Proposed Rule Addresses Fermented and Hydrolyzed Foods with Gluten-Free Claims

The U.S. Food and Drug Administration (FDA) **plans** to set requirements for fermented and hydrolyzed foods or those containing fermented or hydrolyzed ingredients and carry the "gluten-free" claim. The proposed rule would apply to foods such as sauerkraut, yogurt, pickles, cheese, green olives, vinegar, and FDA-regulated beers.

Intended to address the uncertainty of interpreting test methods in terms of intact gluten, the finalized rule would mandate manufacturers to maintain records demonstrating: (i) "the food meets the requirements of the gluten-free labeling final rule prior to fermentation or hydrolysis; (ii) "the manufacturer has adequately evaluated its process for any potential gluten cross-contact"; and (iii) "where a potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process." The agency also intends to evaluate the compliance of distilled foods by using scientifically valid methods to determine the absence of protein or protein fragments. Comments will be accepted until February 16, 2016. *See Federal Register*, November 18, 2015.

FSIS Issues Updated Guidance for Meat and Poultry Product Allergens

Responding to public comments solicited in April 2014, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **issued** revised guidance for identifying, controlling and labeling allergens and other ingredients of public health concern through hazard analysis and critical control point (HACCP) plans, sanitation standard operating procedures (SOPs) or other prerequisite programs. Geared toward meat and poultry products, the **guidance** seeks to ensure "that product labels declare all ingredients, as required in the regulations, and that the product does not contain undeclared allergens or other undeclared ingredients." *See Federal Register*, November 16, 2015.

"Eco-Friendly" Meal Delivery Packaging Claims Should Be Discontinued, NAD Rules

After a review by the National Advertising Division (NAD), the advertising industry's self-regulation investigative arm, Gobble, Inc. has agreed to discontinue claims that packaging for its meal-delivery services is "eco-friendly." NAD requested substantiation for several claims

appearing on Gobble's website, including the company's use of "insulated liners that are biodegradable so that you can dispose of them in your trash with minimal impact on the environment." In response to the inquiry, Gobble stated it would permanently and voluntarily withdraw its packaging claims of biodegradability and eco-friendliness, but noted it had a good-faith belief that the claims were true when first publishing them.

NAD Refers "Danish" Cookie Controversy to FDA, FTC

The National Advertising Division (NAD), an investigative unit of the U.S. advertising industry's system of self-regulation, has referred to the U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC) an ad campaign for Danisa "Traditional Butter Cookies," which are manufactured by the Mayora Group in Indonesia and distributed by Takari International, Inc. NAD evaluated the campaign in April 2015 after Campbell Soup Co. challenged several aspects of the product's marketing, including the claim that the cookies are "produced and packed in Denmark" and "baked following the original recipe from Denmark," as well as the use of Scandinavian imagery. Further, Campbell argued that FDA requires any product labeled as "Butter Cookies" to use only butter as a shortening ingredient, but multiple independent studies have shown the presence of a non-butter fat ingredient in the Danisa product.

Takari International argued it could not be liable for packaging claims or discrepancies in the ingredients, but NAD disagreed, recommending Takari discontinue the challenged claims. While noting its objections, the company agreed to stop advertising the product and promised to stop purchasing the cookies in the future. During NAD's later compliance inquiry, Takari told the board that the product is "a completely new product" not reviewed by NAD. The board found that Takari "failed to provide NAD with any substantiation of this fact—save for anecdotal evidence," and the product continued to feature "Danish costumers, crowns, and other Scandinavian settings that NAD recommended be discontinued." Accordingly, the board referred the marketing campaign to FDA and FTC for further review.

LITIGATION

Ohio Federal Court Dismisses Several Claims in Tito's "Handmade" Suit

An Ohio federal court has dismissed fraud and consumer-protection claims against Fifth Dimension, maker of Tito's Handmade Vodka®, in a putative class action alleging the beverage company misrepresents the process of making its vodka by calling the product "handmade." *Terlesky v. Fifth Dimension*, No. 15-0374 (S.D. Ohio, W. Div., order entered November 17, 2015).

The court analyzed each claim, first finding that the plaintiff did not have standing to sue under the Ohio Deceptive Trade Practices Act. Turning to the Ohio Consumer Sales Protection Act, the court determined that plaintiffs bringing class claims must show the alleged violation was declared to be deceptive by the attorney general or a court before the transaction. Finding no such facts in the case, the court dismissed the class claim but allowed the individual claim to proceed. The court also allowed the plaintiff's promissory estoppel claim to continue.

Turning then to the negligent misrepresentation claim, the court agreed with Fifth Dimension in its argument that a plaintiff "may not maintain an action for negligent misrepresentation when the alleged misrepresentation is intended to reach an extensive, unresolved class of persons" rather than a limited class. The court also dismissed the fraud claim because the plaintiff alleged an economic harm only, not a physical or psychological injury. Quoting a 2003 decision, the court found that "to allow such claims to proceed would be to eradicate the viability of the tort system by overcompensating buyers and creating inefficient incentives for manufacturers."

Plaintiff in Multiple *Trans* Fat Lawsuits Cannot Claim Lack of Subject Knowledge, Court Finds

A California federal court has granted a motion to dismiss claims that La Tapatia Tortilleria mislabels its food as containing no *trans* fats despite containing partially hydrogenated oil (PHO) based on the finding that the plaintiff cannot claim he relied on the product packaging because he is the plaintiff in several similar lawsuits, showing he had sufficient knowledge to determine whether the product contained *trans* fats before purchasing. *Guttmann v. La Tapatia Tortilleria, Inc.*, No. 15-2042 (N.D. Cal., order entered November 18, 2015).

The plaintiff alleged he relied on the "0g Trans Fat" representation on La Tapatia's tortilla packaging when purchasing, then later learned the product contained *trans* fat. He, however, "was amply aware, given his litigation history: (1) that products labeled as "0g Trans Fat" may in fact contain small amounts of trans-fat; (2) that FDA regulations do not require trans-fat content to be declared in the nutrition-facts panel on a product label; (3) that PHO is a form of artificial trans-fat; and (4) that consumption of artificial trans-fat may pose health risks," the court held. Accordingly, the court dismissed the plaintiff's claims brought under California's consumer-protection statutes, but concluded the plaintiff sufficiently established standing to sue for his breach of warranties claims, so it allowed those claims to continue.

Proposed Class Action Challenges Whole Foods Kombucha

Two consumers have filed a putative class action alleging that two lines of kombucha manufactured by Millennium Products and sold by Whole Foods Market contain several defects, including levels of alcohol higher than the label represents and packaging inadequate to properly accommodate the product's secondary fermentation. *Pedro v. Millennium Prods., Inc.*, No. 15-5253 (N.D. Cal., filed November 17, 2015).

Millennium's kombucha, a fermented tea product, is sold in two lines—a "Classic" line requiring the purchaser to be 21 years old and an "Enlightened" line containing "a trace amount of alcohol" but insufficient amounts to require identification upon purchase (less than 0.05 percent alcohol by volume). The plaintiffs allege that both lines contain more alcohol than the label indicates, which allegedly caused one plaintiff to become sick and experience "among other things, trouble breathing, and increased heart rate."

The plaintiffs further allege the byproduct of kombucha's fermentation, carbon dioxide, builds up inside the bottle, which can result in explosions upon opening the product. One plaintiff alleges the product packaging has leaked while in her purse on multiple occasions, causing damage to her purses and their contents. The complaint cites a number of web resources, including blog posts, Facebook and Yahoo! Answers, to argue that many other purchasers of kombucha have experienced similar issues. The plaintiffs seek class certification, an injunction, restitution, damages and attorney's fees for alleged violations of California's consumer-protection statutes.

OTHER DEVELOPMENTS

Precautionary Principle Focus of Upcoming TACD Forum

London-based Trans Atlantic Consumer Dialogue (TACD), a collaborative group of U.S. and E.U. consumer organizations that develops and submits joint consumer policy recommendations to the U.S. government and European Union, is hosting a January 26, 2016, **meeting** in Brussels, Belgium, focusing on use of the precautionary principle in the Transatlantic Trade and Investment Partnership.

Discussions at the event will include an overview of the precautionary principle in trade agreements and how it is used in the United States and European Union; and precautionary approaches to food safety (e.g., BSE, GMO, hormones, GRAS), pesticide/biocide regulation, digital and privacy rights, and intellectual property. Speakers will include U.S. Federal Trade Commissioner Julie Brill and E.U. Trade Commissioner Cecilia Malmström.

Cornucopia Institute Unleashes Attack on Pet Food Manufacturers

A new **report** from Cornucopia Institute, a "non-profit food/farm policy research group," contends the "pet food industry is no different than leading marketers of processed human food when it comes to cheap substitutes and false health claims."

Titled "Decoding Pet Food: Adulteration, Toxic Ingredients, and the Best Choices for Your Companion Animals," the report is accompanied by a product **buying guide**. *See Cornucopia Institute News Release*, November 18, 2015.