ISSUE 733 | December 06, 2019

LEGISLATION, REGULATIONS & STANDARDS

FDA Issues Warning Letters, Consumer Update on CBD, Sparking Litigation Against CBD Cos.

The U.S. Food and Drug Administration (FDA) has issued a consumer update on cannabidiol (CBD) products and other products containing ingredients derived from cannabis. The update clarified that FDA "is concerned that people may mistakenly believe that trying CBD 'can't hurt'" because the agency has "seen only limited data about CBD's safety and these data point to real risks that need to be considered." FDA warned that CBD may have potential to injure the liver, cause negative drug interactions and affect male reproductive health, safety risks the agency identified during its review for the drug form of CBD.

FDA's update coincided with the release of several warning letters to CBD companies from the agency's Center for Drug Evaluation and Research. The letters warned companies that the language used to describe the benefits of CBD amounted to adulterated foods and misbranded drugs.

Following the November 25, 2019, update, consumers filed several lawsuits in multiple states alleging the CBD products they had purchased violated consumer-protection statutes because the products are illegal. *DaSilva v. Infinite Prod. Co.*, No. 19-10148

(C.D. Cal., filed November 27, 2019); *McCarthy v. Charlotte's Web Holdings*, No. 19-7836 (N.D. Cal., filed November 20, 2019); *Colette v. CV Sciences Inc.*, No. 19-10227 (C.D. Cal., filed December 3, 2019); *Ballard v. Bhang Corp.*, No. 19-2329 (C.D. Cal., filed December 4, 2019); McCarthy v. Elixinol LLC, No. 19-7948 (N.D. Cal., filed December 4, 2019).

Companies and Owners Plead Guilty to Seafood Fraud

The U.S. Department of Justice has announced that Roy Tuccillo, Sr., his son Roy Tuccillo, Jr., and their food processing and distribution companies, Anchor Frozen Foods Inc. and Advanced Frozen Foods Inc., have pleaded guilty to conspiracy to commit wire fraud. The companies reportedly imported 113,000 pounds of squid and sold it as octopus to more than ten grocery stores. The father and son could face up to five years of imprisonment and fines up to $250,000, while their companies may be required to pay a fine of up to $500,000 and face five years of probation.

CFS Petitions USDA on Drug Residues

The Center for Food Safety (CFS) has filed a petition urging the U.S. Department of Agriculture (USDA) to provide transparency on the levels of drug residue in meat, poultry and egg products found as part of the agency's National Residue Program (NRP). The advocacy group specifically requests that all approved animal drugs be incorporated in the NRP; that the NRP use "the best available methods that provide for the lowest limits of detection and quantitation"; that USDA establish "clear definitions and parameters for minimum levels of applicability"; and that the agency "improve the NRP reporting mechanisms to provide publicly-available information on all samples with positive residues regardless of whether the levels detected exceed minimum levels of applicability or [U.S. Food and Drug Administration] tolerances."

GAO Recommends FDA Establish Sampling Process for Seafood Imports

816.559.2497
manstoetter@shb.com

M. Katie Gates Calderon
816.559.2419
kgcalderon@shb.com

Lindsey Heinz
816.559.2681
lheinz@shb.com

James P. Muehlberger
816.559.2372
jmuehlberger@shb.com

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.

The Government Accountability Office (GAO) has released a recommendation that the U.S. Food and Drug Administration (FDA) establish a process that ensures the agency tests at least one shipment of imported seafood before removing it from alert status. GAO reviewed 274 removal decisions between 2011 and 2018 and found that FDA did not conduct audits for 260, or 95%, of the decisions.

"FDA officials said they conducted limited sampling because many import alert removal decisions can be supported by documentary evidence provided by firms," GAO announced. "Additionally, for certain violations that indicate a firm failed to meet regulatory or administrative requirements and may pose a public health hazard, an FDA directive establishes a goal for FDA staff to conduct a follow-up inspection within 6 months. However, GAO's review of removal decisions found that for 31 of the 32 firms that received such a finding, FDA did not conduct a follow-up inspection before removing them from an import alert. FDA officials said they did not know whether they were meeting their audit goals because the agency does not have a process to monitor the extent to which it is conducting its sampling and inspections. Establishing such a process would provide greater assurance that FDA is conducting its expected level of sampling and inspections to support its removal decisions and has confidence in continued compliance."

EU Bans Insecticide Chlorpyrifos

A regulatory committee of the European Union has reportedly voted to prohibit the use of chlorpyrifos and chlorpyrifos-methyl. Member countries voted to withdraw authorization for the insecticide after January 31, 2020, after which companies will have three months to dispose of their stocks of chlorpyrifos. The vote follows an August 2019 determination by the European Food Safety Authority finding that chlorpyrifos has "no safe exposure level."

LITIGATION

Pork Producers Sue California over Proposition 12

The National Pork Producers Council and American Farm Bureau Federation have filed a lawsuit against the secretary of the California Department of Food and Agriculture alleging that Proposition 12, which was passed in November 2018 and established minimum requirements for the confinement of farm animals, "has thrown a giant wrench into the workings of the interstate market in pork." *Nat'l Pork Producers Council v. Ross*, No. 19-2324 (S.D. Cal., filed December 5, 2019). The complaint alleges that "Proposition 12 institutes a wholesale change in how pork is raised and marketed in this country. Its requirements are inconsistent with industry practices and standards, generations of producer experience, scientific research, and the standards set by other states. They impose on producers costly mandates that substantially interfere with commerce among the states in hogs and whole pork meat. And they impose these enormous costs on pork producers, which will ultimately increase costs for American consumers, making it more difficult for families on a budget to afford this important source of protein. And they do all this for reasons that are both fallacious and vastly outweighed by the economic and social burdens the law imposes on out-of-state producers and consumers and on the authority of other states over their domestic producers." The plaintiffs urge the court to hold that Proposition 12 is an impermissible extraterritorial regulation and excessive burden on interstate commerce in relation to putative local benefits.

Pringles Salt & Vinegar Lawsuit Denied Certification

A New York federal court has denied class certification to a group of consumers alleging that they were misled by Kellogg Co.'s Pringles Salt & Vinegar chips label into believing the product contained no artificial ingredients. *Marotto v. Kellogg Co.*, No. 18-3545 (S.D.N.Y., entered December 5, 2019). The plaintiff identified himself as a chef who has a deep knowledge of molecular gastronomy and is married to an attorney who works at a law firm seeking to represent the putative class. "Unfortunately, for [the plaintiff], once he popped, the fun did, ultimately, stop," the court noted, explaining that the plaintiff stated he was misled by the sodium diacetate and malic acid on the ingredient list.

The court found that the plaintiff "plainly failed to satisfy the predominance requirement" because only four of 20 Pringles labels contained the challenged "No Artificial Flavors" label. "How is the Court supposed to sift through tens of thousands of individuals to find the subset that has in fact seen the 'No Artificial Flavors' label? If would-be class members claim to have seen the label but lack a receipt from their Pringles purchase, is the Court obligated to hold a hearing to evaluate each individual's credibility? Even if a would-be class member has a receipt proving a purchase of a Pringles can with the 'No Artificial Flavors' label, is a hearing nonetheless needed to confirm that the class member in fact looked at the miniscule back-of-the-can lettering? Unwieldy individual issues clearly predominate." Accordingly, the court denied class certification.

Clif Bar White Chocolate Suit to Continue

A California federal court has denied Clif Bar & Co.'s motion to dismiss a lawsuit alleging that its products marketed as containing white chocolate lack the claimed ingredients. *Joslin v. Clif Bar & Co.*, No. 18-4941 (N.D. Cal., entered December 2, 2019). A previous version of the complaint was dismissed for failure to show that members of the public were likely to be deceived. The court again found that the plaintiffs failed to allege standing for the injunctive relief they sought, but it held that the amended complaint properly alleged facts that satisfy the "reasonable consumer" standard. "This is a close case," the court stated. "Having considered Plaintiffs' amendments, the Court concludes Plaintiffs have nudged their claims over the line from possible to plausible. The Court concludes Plaintiffs' allegations are sufficient to allege the Products' labels would be likely to deceive a reasonable consumer and sufficiently allege facts to state a claim under the unlawful prong of the [California Unfair Competition Law]."

EU Court Denies "Balsamic" as Protected Designation of Origin

The European Court of Justice has reportedly held that "balsamic" as a descriptor for vinegar is not reserved exclusively for producers in Modena, Italy. The case challenged a German

vinegar producer's use of "Balsamico" and "Deutscher Balsamico." Although "Balsamic Vinegar from Modena" has been a geographic indication within the European Union for more than a decade, the court held, the rights to exclusive use did not extend to each word within the phrase. "The term 'aceto' [vinegar] is a common term and the term 'balsamico' [balsamic] is an adjective that is commonly used to refer to a vinegar with a bitter-sweet flavour," the court reportedly held.