

Food Law UPDATE

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FTC SETTLES “MADE IN USA” MISLABELING CLAIMS

The Federal Trade Commission has settled “Made in USA” mislabeling claims against five manufacturers of over-the-counter (“OTC”) pain relievers. The FTC had claimed the five companies used imported active ingredients (bulk aspirin, acetaminophen and ibuprofen) that constitute a substantial portion of the total cost of the finished products. The FTC alleged that the labeling at issue violated the Commission’s standard that “Made in USA” claims be supported by evidence establishing that the product is “all or virtually all” domestically manufactured.

All of the companies involved in the settlements make private label pain relievers for major retailers such as Kmart, Wal-Mart, Target, Costco and Walgreen’s. Apart from the “Made in USA” claims on the labels, a number of the products prominently displayed the American flag on the outer packaging. “American consumers are more sensitive than ever to claims that a product is made in America. If a company chooses to make an American-made claim, it should comply with the Commission’s standard. Here, the high level and nature of the foreign content exceeded any reasonable expectation of the meaning of ‘Made in USA,’” said Howard Bates, Director of the FTC’s Bureau of Consumer Protection.

In this case, the FTC based its allegations on the fact that the imported bulk ingredients at issue comprised a substantial percentage of total manufacturing costs and imparted the crucial analgesic quality to the OTC products at issue. Each of the settlements prohibited the companies from future misrepresentations on the extent to which their OTC products contain domestic analgesics. The

settlements provide a “safe harbor” that allows the “Made in USA” claim so long as all, or virtually all, of the ingredients are made in the United States and all, or virtually all, labor employed to manufacture the product is performed in the U.S. The order does allow the companies to represent that products containing imported active ingredients are “Processed in the United States with Foreign Ingredients,” if the product has been “significantly processed” in the U.S.

The FTC rules do not set requirements for country-of-origin labeling rules. Those rules are separately promulgated and enforced by the U.S. Customs Service pursuant to the Tariff Act. However, the FTC has jurisdiction over foreign origin claims on products and in packaging that are beyond the disclosures required by Customs. The FTC also has jurisdiction over foreign origin claims made in advertisements or other promotional materials.

Practice Note: Please contact us for a more complete analysis and explanation of “Made in USA” and “country-of-origin” labeling rules that may apply to your business.

Food Law Update is published periodically by Zackler & Associates as a service to clients and friends of the Firm. Articles are intended only to be summaries of the law and should not be relied upon as substitutes for legal consultation. For further information or details on any matters discussed in articles, please call Allan Zackler, Steven Weinstein or Matthew Frank at (510) 834-4400.

USDA MOVES TO ELIMINATE FROZEN MEAT PIZZA STANDARD OF IDENTITY

The USDA has set January 2, 2002 as the last day to submit public comment on its proposal to eliminate its decades-old “standard of identity” for frozen meat pizza. Under the current USDA rules, a frozen meat pizza product must have a crust, cheese, a tomato based sauce and at least 10% meat by weight in order to be labeled as pizza. If the standard of identity is eliminated, frozen meat pizzas could then contain as little as 2% meat, the current USDA minimum content required for anything labeled as a meat product.

Assuming USDA goes forward with its plan to eliminate these rules, pizza makers could reduce the amount of meat and experiment with different toppings such as pesto or alfredo sauce. Frozen pizzas that contain no meat are subject to regulations from the Food and Drug Administration. The FDA does not set standard of identity rules for meatless pizzas, allowing manufacturers more freedom in experimenting with different toppings and styles. Neither the USDA nor FDA has jurisdiction over restaurant or delivery pizzas.

FDA / INTERNET LABELING

FDA ASSERTS LABELING REGULATION JURISDICTION OVER WEBSITE CONTENT

In response to a citizen petition from the Washington Legal Foundation (“WLF”), the FDA has asserted its jurisdiction to regulate certain information on companies’ Internet websites under its statutory “labeling” authority. The April 16, 2001 letter from the WLF asked the FDA to “formally adopt a rule, policy or guidance stating that information presented or available on a company’s Internet website, including hyperlinks to other third party sites, does not constitute ‘labeling,’” as defined under the Federal Food Drug and Cosmetic Act. The petition further asked for a rule, policy or guidance from the FDA that such website information may, but does not

necessarily, constitute advertising. Alternatively, the WLF requested that FDA exempt Internet information of food companies from the labeling regulations.

The FDA responded to the petition by letter on November 1, 2001, asserting it had the power to regulate Internet sites. FDA justified its regulatory authority by citing a 1948 Supreme Court case that which stated that material “accompanying” a regulated article does not have to be “attached” to the product to be considered “labeling.” The court said it was the “textual relationship that is significant.” Types of labeling that have been regulated under this standard include brochures, booklets, films and audio recordings.

FDA stressed that it is not seeking to regulate all websites and will look at each issue on a case-by-case basis. For example, the FDA said it would likely assert its labeling jurisdiction when a regulated company used its own website to promote and sell a regulated product directly from the site. On the other hand, FDA stated that third-party websites providing product-specific information similar to traditional advertisements in print media would not be regulated under the labeling rules. Further, FDA said it saw no reason to treat the Internet information from food companies any differently than other FDA-regulated industries. However, FDA declined to issue any formal written rules or guidelines on this policy. Companies wishing guidance on any specific Internet plans were encouraged to consult with FDA prior to launching the promotion.

Practice note: Zackler & Associates will be pleased to review your website to determine whether it presents risks under this new FDA policy.

DIETARY SUPPLEMENTS

FDA ISSUES WARNING OVER LIPOKINETIX

The FDA has warned consumers to immediately stop using the dietary supplement Lipokinetix®, marketed by Syntrox Innovations, Inc. The warning was issued after FDA received multiple reports of liver damage from consumers who were taking the supplement. Lipokinetix is marketed as a weight loss product. Its contains the ingredients norephedrine, caffeine, yohimbine,

diodothyronine and sodium usniate. All reported liver injuries appeared in consumers between the ages of 20 and 32. Onset of damage took as long as three months to occur. Symptoms included nausea, weakness or fatigue, abdominal pain or any change in skin color.

NATIONAL FOOTBALL LEAGUE BANS EPHEDRINE USE

The National Football League has banned the use of the dietary supplement ephedrine by its players. The FDA has linked the stimulant to at least 80 deaths.

Under the ban, which will be included in the league's anti-steroid policy, players will be subject to year-round random testing for ephedrine. Further, the league will ban teams and players from endorsing manufacturers or distributors of ephedrine-based products. Many athletes have used ephedrine-based supplements for both weight loss and energy boosting. The National Collegiate Athletic Association and the International Olympic Committee have long banned the use of ephedrine supplements by its athletes.

STARBUCKS ACCUSED OF SPIKING TEA WITH EPHEDRINE

The Council for Education and Research on Toxics, a Los Angeles based public interest group, has filed suit against Starbucks Corp., claiming that Starbucks has secretly spiked its Tazo Chai Tea with ephedrine since 1996. The lawsuit claims violations of the California Health & Safety and Business & Professions Codes. The Council seeks to enjoin Starbucks from adding ephedrine to the tea and to force Starbucks to pay restitution to the State of California.

While ephedrine is legal for use in dietary supplements, the FDA has not approved ephedrine's use in food or beverage products under its "Generally Regarded As Safe (GRAS)" regulations.

Starbucks has strongly denied the allegations. "We have tested Chai Tea for the presence of ephedrine and the results have been conclusively negative," said Starbucks spokesperson Audrey Lincoff. "Ephedrine has never been used as an ingredient in Tazo's Chai Tea or any other Tazo product. There are no basis to the claims raised by

the plaintiff and we intend to vigorously defend the lawsuit."

ANTI-TRUST

FTC SUES TO BLOCK SEAGRAM DEAL

Citing concerns that a proposed agreement to acquire Seagram's wine and spirit business will lead to less competition in the sale and distribution of rum, the Federal Trade Commission has brought suit in October 2001 to block the transaction. Under the proposed deal, Diageo PLC and Pernod Ricard S.A. were to jointly acquire the assets of Vivendi Universal S.A.'s Seagram Wine and Spirits business. Seagram and Diageo are currently the number two and three sellers of rum in the United States. The number one seller of rum in the U.S. market is Bicardi. FTC alleges that if the deal were to be approved, the new number three rum distributor would have only a two-percent market share, leaving the Bicardi and Diageo/Seagram with effective duopoly control of the rum market.

"The proposed merger would consolidate the second and third largest U.S. rum producers, leaving only two large sellers of rum in the United States. This will create a dangerous likelihood of reduced competition and higher prices for the consumers of rum," said Joe Simons, the Director of the FTC Bureau of Competition.

All the companies involved in the transaction are hoping to resolve FTC concerns and reach a settlement before the case comes to trial. If the deal were allowed to proceed, Diageo, the world's number one alcohol and spirits company, would acquire 61% of Seagram's liquor assets, including Crown Royal, VO Canadian whiskeys, Captain Morgan and Myers rums, 7 Crown American whisky and Sterling Vineyards. Pernod would get the remainder of Seagram's alcohol business, including Chivas Regal, Glen Grant, Royal Salute and Glenlivet whiskies, Seagram's Extra Dry gin and Martell cognac. Earlier this year, the deal was approved by European regulators after the acquiring companies agreed to divest certain Seagram's assets including Sandeman ports and sherries and Seagram's coolers and mixers divisions.

FTC APPROVES NESTLE PURCHASE OF RALSTON PURINA

On December 11, 2001, the FTC approved a proposed consent decree that will allow Nestle Holdings, Inc. to complete its \$10.3 billion purchase of Ralston Purina Company. FTC said the consent decree ensures that the combined companies will not control the dry cat food market in the United States. Under the consent decree, Nestle has agreed to divest Ralston Purina's Meow Mix and Alley Cat brands to J.W. Childs Equity Partners (d.b.a. Hartz Mountain). Nestle has also agreed to relinquish its international trademarks in the brands and to co-pack both brands for Childs for up to two years. Childs has agreed not to re-sell the cat food assets for five years without the FTC's consent.

"Without the terms provided by this consent decree, Nestle would acquire, among other things, Meow Mix, the best selling cat food brand in the country, and as a result would have nearly a 45% share of the U.S. dry cat food market across all levels of distribution. The order will ensure that Childs becomes a strong competitor in the market for dry cat food, to the benefit of consumers nationwide," said the FTC's Joe Simons. Nestle's current pet food business includes the Friskies, Fancy Feast, Mighty Dog and Alpo brands. Ralston Purina's remaining pet food brands include Dog Chow, Cat Chow and Purina Special Care. Even after the divestments, Nestle will now control 45% of the U.S. pet food market.

TRADEMARKS

SWEDISH "APHRODISIAC" DRINK NIAGRA CHANGES NAME

Under legal pressure from Pfizer, the manufacturer of the anti-impotence drug Viagra®, the makers of the Swedish energy drink Niagra have decided to change the name of their product to NEXCITE. The carbonated energy drink, marketed in a suggestively styled blue bottle, was touted by press reports as the "female Viagra."

Sales of the soft drink took off after the Niagra product was featured on ABC's Good Morning America. However, Pfizer quickly sued Niagra's manufacturer and distributor for infringement of Pfizer's Viagra® mark.

Pfizer's infringement action is still pending in federal district court in Little Rock, Arkansas.

Practice note: Zackler & Associates can review your company's proposed trademarks for potential risks of infringement.

ADVERTISING

SoBe BEVERAGE AGREES TO ALTER WEIGHT- LOSS CLAIMS

South Beach Beverage Company ("SoBe"), a unit of PepsiCo, has agreed to remove certain weight-loss claims on print advertisements for its "SoBe Lean" beverage line after the National Advertising Division of the Council of Better Business Bureaus Inc. ("NAD") raised concerns that the ads conveyed the message that drinking a SoBe Lean beverage would, by itself, help consumers lose weight. The offending print ads used phrases like "Fat Burning," "Get Lean, Get Results" and "Metabolic Enhancer." NAD issued the letter to SoBe because it was concerned that the weight loss claims suggested a greater performance benefit than the low calorie products could deliver.

PROMOTIONS

21 INDICTED IN McDONALDS GAME FRAUD

The U.S. Justice Department has indicted 21 people for allegedly defrauding McDonald's restaurants of more than \$20 million by rigging its game promotions. Jerome Jacobson, a regional security official with Simon Marketing Inc., the company contracted by McDonald's to run the games, allegedly hatched the scheme in 1995.

Prosecutors overseeing the FBI investigation said wiretap evidence established that Jacobson distributed winning game pieces to friends, relatives or associates who would then claim themselves legitimate winners of up to \$1 million. The proceeds would then be distributed among the conspirators. So far, the FBI has identified nine separate games that were fixed by the Jacobson ring, including a "Monopoly" game and the "Who Wants to Be a Millionaire" contest.

In response to the allegations, McDonald's terminated its relationship with Simon Marketing and ran a \$10

million "Instant Give-Away" promotion over the Labor Day weekend.

IRRADIATION / ANTHRAX

**SEC ORDERS CHEESE
MANUFACTURER TO CEASE
ANTHRAX NEUTRALIZATION
CLAIMS**

The Securities and Exchange Commission has approved a consent decree ordering a Florida based cheese manufacturer to cease-and-desist from making claims that its irradiation system could kill anthrax bacteria in the mail.

On October 11th and 12th, the Classica Group of Lakewood, Florida issued two press releases claiming that its proprietary microwave technology, normally used to kill bacteria in cheese processing, was "absolutely capable of killing anthrax" in the mail. The day after the second press release Classica's share price rose by more than 10%. The SEC alleged that these statements were false because Classica never tested its technology on anthrax contaminated mail. Since the press releases, Classica has done some successful testing on eliminating a "stand-in bacteria" packed in envelopes.

"The conduct that led to these enforcement actions is reprehensible. Any effort to profit by spreading false information that plays on people's fears is unconscionable," said SEC enforcement official Stephen Cutler.

**HOLIDAY WISHES
TO OUR READERS**

Zackler & Associates would like to take this opportunity to wish all of our clients and friends a joyous Holiday season and best wishes for the New Year. Normally, we would have already mailed holiday greetings to you. However, in light of the relief needs facing our country in the wake of the terrorist attacks, we decided to forgo the expense of mailing cards and instead made a special contribution to the American Red Cross.

Zackler & Associates provides a full range of legal services to clients in the food, nutrient supplement, consumer products, advertising and marketing consulting industries and importers/exporters. Our involvement in the areas of consumer packaged goods, food labeling and other food regulatory requirements dates to the mid-1970's. We look forward to serving your legal needs in the future. Please call us at (510) 834-4400:

- ◆ Packaging and Labeling/NLEA Compliance
- ◆ Food Regulatory Matters-Federal & State Agencies
- ◆ Dietary Supplement/Vitamin Regulation
- ◆ Marketing and Promotion Programs
- ◆ Advertising Review
- ◆ Trademarks Registration and Protection
- ◆ Technology Licensing Agreements
- ◆ Contract Negotiation and Preparation
- ◆ Incorporations, Partnerships & L.L.C.'s
- ◆ Customs Law; International Trade Regulation
- ◆ New Product Development/Regulatory Concerns
- ◆ Antitrust and Corporate Compliance Review
- ◆ Drug, Cosmetic & Medical Device Issues
- ◆ Energy Issues
- ◆ Distribution Law