ZACKLER & ASSOCIATES

Food & Marketing Law Update

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Inside this Edition of Food & Marketing Law Update....

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FDA Publishes Second & Final Set of Proposed Bioterrorism Rules

The FDA has published for comment its second and final set of proposed rules to implement the mandates of the 2002 Bioterrorism Act. As reported in the Winter 2003 issue of *Food & Marketing Law Update*, the agency previously published rules pertaining to facility registration and prior notice to the FDA of the importation of food products into the United States. The new proposed rules cover record keeping requirements for the receipt and shipment of food from processor to retailer and the circumstances and procedures under which the FDA can administratively detain inventories of food products.

The record keeping rules apply to "non-transporters" such as processors and distributors and "transporters" such as independent trucking companies and public warehouses. Subject to certain exemptions, including exemptions for farms, restaurants and USDA inspected firms, the rules apply to both foreign facilities and domestic companies (whether or not they operate a facility) who are engaged in the food business. Non-transporters must keep records pertaining to (i) the immediate previous source ("IPS") of a food or a food ingredient and (ii) the immediate subsequent recipient ("ISR") of its products. Transporters must keep records pertaining to the identification of the shippers and the recipients of food products. The rule requires detailed records to tie specific food products with the firms that made, handled or received them. During normal business hours, FDA inspectors must be given access to these records within four

Bioterrorism Act (Cont'd on p.3)

Will You Be Ready When the New Bioterrorism Rules Go Into Effect?

December 12 is just a few months away. Zackler & Associates has prepared a presentation for owners, managers and the technical staffs of food and transportation companies that summarizes the new rules. Zackler & Associates is also available to work with your company to review your current operational procedures and develop and implement with you any needed changes to ensure your compliance with the new rules. Remember non-compliance can result in stiff penalties along with significant disruption of your operations. Call us for more information.

Rigged Frozen Coke Marketing Test Prompts Settlement Offer and Criminal Investigation

Soft drink giant Coca Cola is feeling the fallout from evidence that its employees rigged market acceptance tests of Frozen Coke. A lawsuit filed by a former Coke manager alleged that Coke marketing employees improperly influenced marketing tests conducted in Burger King restaurants three years ago by paying customers to purchase Value Meals featuring Frozen Coke in test markets. The inflated sales data generated from the tests prompted Burger King franchisees to purchase over $65 Million in Frozen Coke equipment for their restaurants. Sales of Frozen Coke in Burger King outlets have not met franchisees' expectations. Coke has admitted that its employees rigged the tests and have offered over $20 million to Burger King and its franchisees to settle any claims.

The accusations have also prompted a criminal investigation from a Federal Grand Jury in Atlanta. Coke acknowledged the criminal probe in July and has pledged to cooperate with the government. Burger King has also acknowledged receiving subpoenas from the Grand Jury. ■

Supreme Court Punts on Karsky Appeal

After hearing oral argument and reading hundreds of briefs, the United States Supreme Court has decided not to decide Nike's appeal of the California Supreme Court's decision in Karsky v. Nike. As reported in prior issues of Food & Marketing Law Update, the California Supreme Court held in Karsky that businesses could be liable under the state's Unfair Practices Act (also known as Business & Professions Code Section 17200) for false public statements that the business makes in connection with public policy issues if those statements might influence a consumer's decision to buy one of the business' products. Nike had defended itself in the lawsuit by arguing that its public statements responding to critics of its use of off shore "sweat shop" labor were protected by the First Amendment.

The United States Supreme Court did not explain the reasons for its actions. However, three justices, Stevens, Souter and Ginsberg wrote a concurring opinion in support of the dismissal. The opinion stated that the appeal was not "ripe" because there remained critical unresolved issues of law and fact that required a trial on the merits. Justices Breyer and O'Conner wrote a dissent stating that the unresolved issues would not affect the outcome of the case and therefore it was in fact ripe for decision by the Court. The remaining Justices—Rhenquist, Thomas, Kennedy, and Scalia—said nothing.

Comment: By our reading, the California Supreme Court's decision in Karsky left no undecided issues of fact or law that should have precluded a decision on the merits by the United States Supreme Court. Under the Unfair Practices Act as applied by the California Supreme Court, a company can be liable if it makes a false statement concerning a public policy issue that might affect a consumer's decision whether to buy the company's product. The only factual issue is whether the statement was false. In any event, Karsky will continue to be the law of California for the foreseeable future. ■

hours of their request. FDA inspectors may request these records if they have a reason to believe that a non-transporter or a transporter handled an adulterated food that presents a serious threat to human or animal health. The FDA has not specified any particular format for collecting, storing or retrieving the required information and has generally assumed that most firms' current record keeping practices will be adequate.

The administrative detention rule gives the FDA the power for the first time in its history to administratively detain (i.e. without a court order) for up to 30 days any food product that presents a serious threat to human or animal health. Subject to the approval of a district director, FDA inspectors may order an administrative detention. The rule also provides for administrative review of a detention order. Note that FDA authority under both this rule and the record keeping rule is not limited to acts of bioterrorism.

As is the case with the facility registration and import notification rules, the record keeping and administrative detention rules will go into affect no later than December 12, 2003. Depending on the size of the business, firms must be in compliance with the record-keeping rule within six to 18 months after the December 12 effective date.

Proposed Importation Notification Rule Modified to Be More User Friendly

The import notification rule as originally proposed by the FDA called for a completely separate FDA only system. After significant negative reaction from industry, the FDA has announced that its system will be integrated with the Bureau of Customs and Border Protection's existing Automated Commercial System ("ACS").

Comment: Combining facilities registration and record keeping requirements creates a traceable trail of custody of food products. Combined with detention authority, this could allow the FDA to target those businesses that have or may have food products that are or are suspected of being a threat of serious adverse health consequences or death to humans or animals. Inspectors could merely contact those businesses in the chain of distribution and order administrative detention.

FDA Adopts New Trans Fat Labeling Rule

In the most significant change in the nutritional labeling rules since the NLEA rules became effective in 1993, the FDA has mandated that "Nutrition Facts" and "Supplement Facts" panels will have to disclose the amount of trans fatty acids in the product. This declaration is to appear immediately below the declaration for saturated fat. For products having less than 5 grams of trans fat per serving, the amount of trans fat should be rounded off to the nearest 0.5 gram and for products with 5 grams or more of trans fat, the rounding should be to the nearest whole gram. Products that contain less than 0.5 grams of trans fat will not be required to declare trans fat if there are no label claims about fat, fatty acid or cholesterol content. However, the products must state in a footnote that they are not "a significant source" of trans fat. Because trans fat is assumed to have no nutritional value, there will no DRV or DV for it. The new rule will become effective on January 1, 2006.

The new rule also contains a series of conforming amendments that integrate the trans fat declaration into the currently permitted variations of the general nutrient labeling requirements such as the qualifications permitting the use of the simplified labeling format. Also, in order to correct an inadvertent omission in the original FDA regulations, saturated fat will have to be declared whenever any nutrient content claim is made about fatty acids.

Pending further review, the FDA has not approved any on-label nutrient content claims about trans fat such as "trans fat free" nor has the FDA specified any benchmark limits that might be imposed on trans fat containing foods making health claims.

Grey Goose and Belvedere Battle over Vodka Ratings

The National Advertising Review Board ("NARB") has ruled that advertisements claiming Grey Goose® Vodka is "Rated the No. 1 Tasting Vodka in the World" are deceptive because they provide "an unfair and inaccurate representation as to a competitor's product, and did not provide consumers with a complete factual picture." The case, brought by the importer of Belvedere® Vodka, did not claim that the 1998 Beverage Testing Institute ("BTI") taste test showing Grey Goose on top of the ratings with a score of 96 was incorrect. Instead, Belvedere claimed that listing of its score of 74 was unfair because subsequent testing since 1998 by BTI showed Belvedere scoring 91 and 92.

The NARB decision recommends that Grey Goose's importer, Sidney Frank Importing Company, either discontinue the comparative reference based on Belvedere's score in the 1998 testing or include Belvedere's most recent score. However, in a statement published by the JustDrinks.Com website, Sidney Frank said it would continue to use the advertising because the NARB decision conflicts with the policies of the BTI which prevent advertisers from making comparisons to different taste tests because such cross test comparisons are invalid. If the Grey Goose ads continue as written, the NARB can choose to ask the Federal Trade Commission or the Bureau of Alcohol, Tobacco and Firearms to enforce its decision.

Practice Note: Companies that choose to conduct comparative advertising campaigns must be vigilant to formulation changes by competitors or subsequent taste tests as those changes can make the advertised taste claim no longer valid. Please contact us if you have any questions on how to structure your comparative advertising claims.

Texas Will Not Appeal Verdict Allowing Direct Wine Shipments

The Texas Alcoholic Beverage Commission has decided against appealing a decision of the 5th U.S. Circuit Court of Appeals allowing direct wine shipments to Texas consumers. Earlier this year the Appeals Court upheld a District Court decision that the Texas regulations prohibiting direct shipments of out of state wines violated the interstate commerce clause of U.S. Constitution. Wholesale distributors, who act as middlemen between producers and consumers and take a cut of all Texas wine sales, had persuaded the Commission to keep the restrictions in spite of efforts from wine consumers to open up the market for direct to consumer shipments. The Commission and wholesalers had maintained throughout the litigation that loosening the rules would make it easier for children to order alcohol. Under the court decision, adult consumers living in parts of Texas that allow alcohol sales can purchase wine from out of state and have it shipped by any of 400 carriers licensed to carry alcoholic beverages in the state such as United Parcel Service. Shipping wine through the U.S. Postal Service is still illegal.

Practice Note: Many other states still have restrictions on direct to consumer wine shipments. Zackler & Associates can provide you with a current listing of wine shipping rules for all 50 states and the District of Columbia.

USDA Publishes Irradiation Specs for Frozen Ground Beef

The USDA has published 19 pages of technical specifications for frozen, irradiated ground beef. Here are the some highlights:

- Radiation sources can include gamma ray, electron beam or x-ray.
- Beef designated for radiation can not be frozen before grinding and must be ground within five days of slaughter.

Frozen Ground Beef (Cont'd on p.5)

Tropicana Agrees to Change Fresh Claim in "Pure Premium Orange Juice" Ad

Tropicana Products, Inc. has agreed to change a television commercial that implied its Pure Premium Orange Juice was the same as fresh squeezed orange juice. Tropicana's change was prompted by a ruling from the National Advertising Division ("NAD") criticizing the ad.

The subject ad opened with a woman saying, "I love everything about fresh squeezed orange juice, except the squeezing part - so I pour myself some Tropicana instead." Tropicana contended that message of the ad was only that Tropicana was a great tasting product and good alternative to squeezing fresh oranges. The competitor challenging the ad before the NAD contended that the commercial implied that Tropicana was identical to fresh squeezed juice. The NAD ruled that text and the images from the commercial would likely confuse consumers into thinking that the Tropicana product was "fresh." This impression would be false because the pasteurized juice did not meet the FDA's definition of "fresh" outlined in 21 CFR Section 195.

Frozen Ground Beef (Cont'd from p.4)

- Irradiated ground beef must be tested for Salmonella and E. coli after irradiation.
- Irradiated fine ground beef must be vacuum packed in thermo formed, tamper proof plastic containers weighing ten pounds.
- Irradiated ground beef patties can be packed in either ten or twenty pound packages.
- Shipping containers must bear marks identifying the beef as irradiated and shall state a "best if used by" date of 180 days from the date of production.
- Products must be maintained in a frozen state from the time of leaving the shipping freezer and throughout the irradiation process.

FDA Rescinds Olestra Labeling Requirement

The FDA has repealed a seven year-old rule that required warning labels on products containing the zero calorie fat substitute Olestra®. Olestra was approved by the FDA in 1996 for use in savory snacks like potato chips, cheese puffs and crackers. Under the old rule, manufacturers were required to inform consumers that Olestra may cause abdominal cramping and loose stools in some individuals, that it inhibits the absorption of vitamins A, D, E and K and that these vitamins have been added to compensate for Olestra's effects on these nutrients.

FDA changed its position based on a scientific review of post-market studies and adverse incident reports. The post-market studies showed that "real life" consumption of products containing Olestra caused only infrequent and mild gastrointestinal effects and that consumers were confused by the message contained in the warning.

European Court Sides with Producers in Geographical Food Names Dispute

The European Court of Justice has resolved a longtime dispute over the use of geographic names on food products. The Court sided with two Italian trade associations that sued over the use of the Parma ham and Grana Padano cheese names on cheeses and hams that had been sliced, grated and packaged outside of their Italian production regions. The Court reasoned that the grating of cheese and the slicing of ham constituted "important operations which may damage the quality and authenticity and consequently the reputations of the geographical names" if those requirements are not followed. As a result of the ruling, distributors or retailers can no longer use geographic designations if they choose to slice, shred or re-package these products outside of the production regions.

FDA Adopts New Procedures for Submittal of "Qualified" Health Claims

Agency Approves Qualified Claims for Nuts

As reported in the Winter 2003 issue of Food & Marketing Law Update, the FDA has been in the process of developing procedures to "approve" qualified health claims for use on both foods and dietary supplements. Although the FDA won't admit it, these changes are apparently in response to the court orders in the Pearson v. Shalala case which was a successful First Amendment challenge to the FDA's limitation on bona fida, on-label health claims.

The regime divides label health claims into four categories:

Rank	Scientific Support for Claim	Qualifiying Language (Suggestive)
A	Significant scientific agreement.	None
B	Evidence is not conclusive.	"although there is scientific evidence suporting the claim, the evidence is not conclusive."
C	Evidence is limited and not conclusive.	"Some scientific evidence suggest...however, FDA has not determined that this evidence is limited and not conclusive."
D	Little scientific evidence supporting claim.	"Very limited and preliminary scientific research suggests...FDA concludes that there is little scientific evidence supporting this claim."

Rank A claims are the legislatively authorized claims under the NLEA which are subject to a rule making process and once approved are published in the Code of Federal Regulations ("CFR"). For more information about currently approved Rank A health claims see Title 21, subpart E of the CFR. The other claims are not legislatively authorized and therefore will be approved through a non-rule making process.

Beginning September 1, 2003 the FDA will begin accepting petitions for qualified health claims. The petitions will be prioritized on such factors as whether the food or dietary supplement is likely to have a significant impact on serious illness and the strength of the evidence supporting the claim. After a 45-day internal review period the FDA will then post the petition for a 60-day public comment period. After the close of the comment period, the FDA can conduct its own review. Within the next 165 days (i.e. within 270 after filing the petition), the FDA will notify the petitioner of its determination.

The FDA will use a six step interim process in evaluating the scientific support for the health claim. These evaluation steps include (a) the relationship between a nutrient and disease, (b) the identification of individual studies concerning this relationship (c) classification of the studies based upon study design type, (d) designation of study quality (e) ranking of the scientific evidence (i.e., A. B, C or D) and (f) reporting the rank. While using this interim procedure, the FDA intends to continue reviewing the inclusion of qualified health claims in its normal rule making process.

FDA APPROVES QUALIFIED CLAIMS FOR NUTS AND CORONARY HEART DISEASE

The FDA identified four "fast track" health claims for approval. These claims are for (i) omega-3 fatty acids reducing the risk of heart disease, (ii) consumption of fruits and vegetables reducing cancer and chronic illness risk, (iii) reducing the risk of heart disease by using vegetable oils containing unsaturated

"*Qualified Health Claims (Cont'd on p.7)*

"Qualified Health Claims (Cont'd from p.6)

fats in place of solid fats and (iv) reducing the risk of heart disease by using nuts as a replacement for proteins containing saturated fat.

On July 14, 2003 the FDA approved a qualified coronary heart disease ("CHD") prevention claim for walnuts and other nuts based upon a petition by the California Walnut Commission. However, the approved qualified claim is different from the claim requested by the Commission. The Commission had petitioned FDA to use the claim "Diets including walnuts can reduce the risk of heart disease." The FDA rejected this proposal because the FDA concluded that there is not significant scientific agreement regarding walnut consumption and a reduced risk of CHD. Instead, the FDA has approved the following qualified claim: "Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. See nutrition information for fat content." At the same time, FDA also approved a wider claim that consumption of peanuts and several kinds of tree nuts will reduce the CHD risk. Note the FDA has prescribed specific language on how each claim is to be stated and has imposed additional disclosure requirements and limitations on the claims' use. ■

Oatrim Added to List of Nutrients That Can Make Health Claim For Fiber and Coronary Heart Disease

In response to a long standing petition from the Quaker Oats Company, the FDA has approved a modification of the existing conventional (non-qualified) health claim linking the consumption of soluble fiber to a reduced risk of coronary heart disease. Effective immediately foods containing oattrim (more technically known as alpha-amylase hydrolyzed oat bran) may make this claim if they meet all of the other requirements in the regulation. ■

Ask Allan (Cont'd from p.8)

written agreements with the idea that none of the people who were responsible for negotiating it will again be available the day after its signed. This is also a check on the completeness and understandability of the document.

Written agreements force the parties to address issues that they might overlook or even try to avoid. Some of these items are referred to as "boiler plate" and include items like indemnification issues. If something goes wrong, who's responsible and for how much? When can the agreement be prematurely terminated, assuming we know its term? If we have a dispute how will it be resolved? Courthouse or arbitration? Where will the dispute be heard, in my hometown or yours?

Note that a written agreement is not a substitute for good deal terms. It's always up to the business people to determine the proper price, quantity, and quality of the products or services they intend to sell or buy. We can write the clearest, cleanest, most complete agreement imaginable for either the best deal you could ever make or the worst deal you could ever make. ■

Eggo Ad Runs Afoul of Children's Advertising Guidelines

Kellogg discontinued a television commercial for its Eggo® Homestyle Waffles after the Children's Advertising Review Unit ("CARU") of the National Advertising Division ("NAD") of the Better Business Bureau ruled that the theme of the commercial was inappropriate for young children. In the commercial, an adolescent boy eating the waffles bullies a puppet after the puppet commented, "It's nice to share." The CARU objected to the ad because the bullying behavior which included pushing the puppet under the table, tying the puppet's shirtsleeves and shoelaces together, and pulling the puppet's legs over his head, was easily duplicable by an older sibling to a younger one, thereby violating Principle 5 of its guidelines urging advertisers to portray beneficial social behavior. ■

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Food & Marketing Law Update

Ask Allan

You lawyers always seem to be so enamored with getting everything in writing, especially agreements. What's the big deal? Telephone calls, handshakes and email have always worked for me.

We recommend written agreements, be they one page letters or multi-page contracts, for the day when the oral or undocumented understanding no longer works. It may no longer work because the parties no longer agree (if they ever really did) as to what they agreed to in the first place. Such disagreements are a fertile source of another thing lawyers do, lawsuits.

To be more specific the benefits of written agreements include:

Mitigation of ambiguity and misunderstanding. We concede that ambiguity and misunderstanding can occur in the otherwise best-written agreement (sometimes deliberately so), but written agreements at least commit the parties to the same piece of paper.

The administration of the agreement can be delegated to people who weren't present at the creation and may not otherwise have a clue as to what the original negotiators agreed to. We always approach

Ask Allan (Cont'd on p.7)

Zackler & Associates Provides the Following Legal Services:

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