ZACKLER & ASSOCIATES

Food & Marketing Law Update

Volume 17, Issue 1, Winter 2003

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

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FDA Begins Implementation of Bioterrorism Act

Virtually Everyone in the Food Business Will Be Affected

On January 29, 2003 the FDA published *Federal Register* notices for two sets of proposed rules to implement two of the four required FDA mandates in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act."). The requirements of these four mandates will fundamentally affect the business practices of many domestic and foreign firms that sell food (including dietary supplements) in the United States.

The two published notices are for rules that (a) require, with certain exceptions, the registration with the FDA of *every* domestic and foreign facility that processes, packs or stores food that is sold in the US and (b) require prior notice to the FDA of every shipment of food imported into the US. The FDA intends to have these rules finalized and its internet based 24/7 registration and import notice systems operational by October 12, 2003. Any person or firm who fails to register a covered facility by December 12, 2003 or who imports of food into the United States after December 12, 2003 without providing prior notice to FDA will be in violation of the act and subject to civil and criminal sanctions.

The FDA has delayed until at least April the publication of the proposed rules to implement the two other mandates in the Bioterrorism Act. One mandate requires that all businesses that manufacture, process, pack, transport, store, or import food into the United States keep a paper trail of all suppliers of the food and the persons to whom the food is sold. We anticipate that these rules will require food manufacturers and processors to keep batch-by-batch records of the sources of ingredients used to make their products. This rule must also be effective no later than December 12, 2003.

The fourth mandate gives the FDA new authority to administratively detain (i.e. without court order) any food that the agency has evidence or information that the food presents a threat of a serious adverse health consequence to either humans or animals. The legislation mandating this rule does not require any association with terrorist threats or activity. There is no deadline for implementation of this rule.

Bioterrorism Act *(cont'd on p.3)*

Food Law Update Has A New Name

Legal compliance begins at home. In order to avoid a charge of "misbranding" we've changed the name of *Food Law Update* to *Food & Marketing Law Update*. This name change reflects that the fact that our newsletter and the legal services offered by Zackler & Associates extend well beyond the issues of food labels and other FDA regulations and include all of the aspects of running a company that markets a food or consumer product such as advertising, promotional activities, trademarks and other intellectual property rights, packing and distribution agreements, competitor issues, corporate formation, dispute resolution, and employment issues.■

New California Organic Law Goes Into Effect

The first significant changes in California's 1990 pioneering organic labeling law became effective on January 1, 2003. The changes conform California law to the National Organic Program ("NOP") rules established by the USDA. The new law is intended to included organic labeling of products not covered by the NOP, specifically cosmetics; but the statutory language as well as the rules that have been promulgated by the California Department of Agriculture include any product that is labeled organic. This would include products such as clothing ■

Racketeering Law Allows Competitors and Employees to Sue Companies Hiring Illegal Workers

RICO Isn't Limited to the Tony Soprano School of Management

In separate decisions two United States Circuit Courts of Appeal have held that competitors and employees of companies that have a business practice of hiring undocumented workers can sue those companies under the Racketeer Influenced and Corrupt Organizations Act of 1970 which is commonly known as RICO. While RICO is far too complex and esoteric to fully explain in this article, one of its requirements is that the defendant engaged in certain "predicate acts," the most common of which are mail and wire fraud. RICO encourages private lawsuits by giving successful plaintiffs treble damage recoveries and reimbursement of their attorney fees.

RICO's coverage of hiring undocumented workers has not been in question because Congress amended RICO to make the knowing hiring of undocumented workers a predicate act. What has been in issue is who could sue a company that had such a engaged in such practices. The Ninth Circuit Court of Appeals recently held in *Mendoza v. Zirkle Fruit Co.* that employees of two Washington State fruit packers could sue their employer for knowingly hiring undocumented workers in order to depress wage rates. Previously the Second Circuit, which is based in New York, held in Commercial *Cleaning Services v. Colin Service Systems* that a janitorial services company could be sued if they hire undocumented workers in order to pay lower wages and thereby under bid its competitors.

Both lawsuits were in part supported by The Federation for American Immigration Reform or FAIR. In a press release FAIR stated that similar lawsuits are pending against Tyson Foods and IBP and that the organization expects many more workers and businesses to take advantage of the rulings.

Note that the occasional hiring of an undocumented worker is not a RICO violation. On the other hand, the deliberate failure to check worker immigration status could be characterized as an intentional scheme under RICO. Zackler & Associates can review your hiring practices for potential RICO related issues.

Now's The Time to File EU Trademark Registrations

Window of Opportunity Closes on April 1, 2003

The unprecedented expansion of the EU to ten new countries effective May 1, 2004 has provided a unique short-term opportunity to file for EU trademark registrations (called a CTM) based upon the EU's current membership of 15 countries. In other words, you get 10 countries for free. Unlimited supplies of this opportunity will last until April 1, 2003.

CTM's filed *before* enlargement will override any existing registrations in the new member nations and also those nations' restrictions on registration. If you have any plans to register marks in Europe there are five reasons to proceed with registration at this time:

1. After enlargement, registration fees will increase by an estimated US $700 per registration.
2. After enlargement, refusals of registration can be based upon descriptiveness or deceptiveness under the languages of the new member states.
3. After enlargement, refusals of registration can be based on pre-existing trademark rights of the new member states.
4. CTM registrations filed on or after November 1, 2003 will be subject to challenge by new member states or any trademark owner in a new member state for the reasons identified in Items 2 & 3.
5. For registrations filed prior to April 1, 2003 our correspondent CTM trademark counsel is reducing its's fees for filing trademark registrations by 25%.

Zackler & Associates has worked with the same CTM trademark counsel for several years and has found that they provide the highest quality of service. We have been able to successfully combine our domestic trademark expertise with that of CTM's counsel to offer efficient and effective international trademark registration services to clients.

Bioterrorism Act *(cont'd from p.1)*

The two proposed rules that have been published by the FDA are far too complex to fully detail in this article. However, some significant items to note are:

Proposed Facility Registration Rule

- Facilities include businesses involved in the production and distribution of food packaging materials.
- Facilities mean specific physical locations such as individual plants, warehouses, or retail stores which also engage in wholesale activities (e.g. Costco).
- Any updates must be reported to the FDA within 30 days.
- All foreign facilities must have a US based agent. (Currently this requirement only applies to foreign drug manufacturers.)
- Exempt from registration are farms (including fish farms) which only engage in the sale of raw agricultural products, restaurants, grocery stores, non-profit food establishments (e.g. soup kitchens and food banks), fishing boats that do not engage in on-board processing, facilities subject to USDA regulation and foreign facilities that send food to other foreign facilities for further processing or packing prior to export to the US. Note that mixed facilities which have both exempt and non-exempt operations must be registered.
- Imported food will not be allowed into the US if it produced at an unregistered, non-exempt foreign facility.

Proposed Import Notification Rule

- Importers will be responsible for compliance with this rule
- This will be a stand-alone system. (The FDA has stated that it will continue to work with US Customs to create a unified system.)
- Shipments of food which have not been registered will be either refused entry or stored at a secure facility at the importer's expense
- The definitions of country of origin and port of entry are different from the Customs definitions
- The notices may be filed no earlier than 3 days before the anticipated entry date of the shipment into the US and no later than noon of the day before entry
- Separate notice will be required for each "article," which appears to be equivalent to an SKU.
- The notices will require up to 13 elements of information including Customs numbers, identification of foreign manufacturer, type of food based on FDA 7 digit product codes, lot code country of origin, identification of importer and carrier
- Certain amendments of the notices as to quantity, port of entry, time of entry will be permitted up to two hours before arrival. No amendments will be allowed as to the type of goods

Obviously, these newly proposed rules and the new rules expected to arrive in April represent a sea change in regulation for many food businesses. The significance of these changes is compounded by the very short fuse to implement them. Zackler & Associates strongly recommends that you now begin examining your business operations to determine how you might be affected by these new rules. We are available to assist you in that examination and in the establishment to new systems to assure seamless compliance when the rules become effective.

Availability of Irradiated Food Products Growing

Liability If You Don't Zap?

Recent articles in the *San Francisco Chronicle* and *The Wall Street Journal* have focused on the significant growth in the sale of irradiated fresh beef products (in part due to last year's mega recalls of ground beef) and the fact FDA appears to be poised to approve radiation for many more classes of products including deli meats. Although irradiation was first approved in 1963, critics of the approval contend there is not sufficient data to establish whether there could be adverse long term health effects of consuming irradiated food products. While the FDA's approvals don't put the food safety issue completely to rest, courts normally defer to a regulatory agency's scientific expertise.

This creates an important issue for producers and retailers of food products who don't use approved radiation methods. Does irradiation create a new industry standard and if you sell a contaminated product could you be liable for punitive damages? A little legal explanation is necessary.

Under modern products liability laws, manufacturers of consumer products are "strictly liable" (liable without fault) for consumer injuries caused by consumption of their products. For example, if a consumer gets sick from eating a packer's ground beef, then the packer is liable and pays for the consumer's out-of-pocket losses, their prospective losses such as future wages and pain and suffering. It doesn't matter whether or not the product was irradiated. However, if a packer "recklessly" or "willfully" exposed an injured consumer to an unwholesome product, then a jury could hold the packer liable for punitive damages. A number of recent notorious product's liability cases have involved punitive damage awards far in excess of the consumer's actual damages. (By the way, under California law you can't insure for reckless or willful misconduct.) We don't think that it takes a good deal of imagination for a sick plaintiff to find their way to an attorney who will claim that a defendant food processor engaged in reckless or willful misconduct by failing to irradiate a product that is known to possibly carry food borne illness. Maybe advertising that product is not irradiated could be an (unintentional) warning label.

By the way, restaurants, whether they sell fast food or slow food, are not subject to strict liability. They are liable for injuries caused by negligence, recklessness or willful misconduct. Of course, any plaintiff's attorney could just claim that a restaurant was negligent if it didn't use irradiated ingredients.

FDA Issues New Policy Statement Concerning Health Claims on Dietary Supplements and Food

Agency Engages in Regulatory Origami

In a new effort to comply with the District of Columbia Court of Appeals decision in *Pearson v. Shalala* the FDA has issued a new policy statement concerning "qualified" health claims that can be put on the labels of dietary supplements and food products. In *Pearson* the Court held that the First Amendment limited FDA's regulation of truthful health claims on the labels of dietary supplements.

Essentially, the FDA's new policy has created a category of "enforcement discretion" for health claims that do not meet the FDA's existing requirement that health claims be substantiated by "significant scientific agreement." The new category is based on the "weight of the scientific evidence". The FDA's policy describes this test as: "The test is not whether the claim is supported numerically (i.e., whether more studies support the proposed claim than not), but rather whether the pertinent data and information presented in those studies is sufficiently scientifically persuasive."

In order to trigger enforcement discretion, the health claim must be submitted to the FDA through its existing petition process for health claims. Presumptively, the FDA will exercise (non-) enforcement discretion, if it determines that although the claim is not supported by "significant scientific agreement," it is supported by the weight of the scientific evidence. The FDA has reserved the right to later exercise enforcement discretion *against* a health claim if it determines that the weight of subsequent scientific evidence shifts against the claim.

Don't rush to file your petition with the FDA. The Office of Nutritional Products, Labeling and Dietary Supplements, which will be administering the program, has stated that qualified claims will not be reviewed by the agency until an implementation phase is completed that could take as long as six months.

This rather peculiar policy is based on the FDA's position that the FD&C Act only allows it to approve health claims that meet the significant scientific agreement test and therefore, the FDA cannot "approve" health claims that a meet a lesser standard.

It remains to be seen whether this new policy will satisfy the plaintiff's contention that prior FDA initiatives failed to comply with the requirements of *Pearson*. Even if the policy itself meets *Pearson's* requirements, there will probably be issues whether the FDA is honestly administrating the new policy. We expect more visits to the courthouse before this is all over.

The FDA's new policy also stated that it is adopting the FTC's "reasonable consumer" standard for determining whether a claim is misleading instead of the statutory "misleading in any particular" standard. We'll have to wait and see how the FDA interprets this new standard and what effect, if any, it has on FDA enforcement actions. However, it's a very good bet that your marketing department's definition of a reasonable consumer won't be the same as the FDA's.

Meanwhile, the FDA has approved a new health claim for products with D-tagalose, which is commonly called tagalose. Tagalose has been added to the "does not promote tooth decay" health claim that the FDA has already approved for products sweetened with sugar alcohols such as sorbitol. As with many FDA regulations there is a catch. Because tagalose is classified as a sugar, products that contain it cannot be labeled as "sugar free." On the other hand, products which contain tagalose will not have to list their sugar alcohols content in the Nutrition Facts. The amended regulation approving the new health claim for tagalose contains several examples of model claims.

Zackler & Associates can advise you concerning utilization of the new FDA policy to expand marketing opportunities for your food and dietary supplements.

Industry Disputes FDA's Proposed Trans Fat Warning Label

The Future Is Here Now

Speaking of a food labeling future of warning labels, in the Summer 2002 issue of *Food Law Update* we commented on a National Academy of Sciences study that concluded the DV for trans fatty acids should be "0" and on the proposed FDA trans fat labeling rule. In that issue we predicted that nutritional warning labels would be the trend of the future. Well, the future is here now. The FDA's proposed trans fat labeling rule not only requires listing the amount of trans fat in a product, it would also require the Nutrition Facts box to have a footnote in 10 point type stating: "Intake of trans fat should be as low as possible." Industry reaction to this proposal is not favorable. It has criticized the proposal as likely to cause consumers to substitute for products that are high in saturated fat, for which no warning is required and the corresponding reformulation of products by food processors. Public interest advocates of the proposal want the warning expanded to include saturated fat. The FDA is expected to issue its final rule this summer.

Fat News

Fat People Lawsuit Against McDonald's is Dismissed

Well Sort Of--Judge Leaves Legal Cookie Jar Door Open for Plaintiffs

In a 64 page opinion US District Judge Robert Sweet dismissed the class action lawsuit that New York City attorney Samuel Hirsch filed against McDonald's on behalf of two obese teenage girls. However, Judge Sweet left the door open for Hirsch to amend his complaint and continue to pursue the lawsuit.

Although Judge Sweet matter-of-factly rejected claims that McDonald's could be liable for selling food which consumers generally know to be unhealthy, he did allow the plaintiffs to reformulate the action to one based health risks in McDonald's food that are known to McDonald's but not disclosed by McDonald's and not generally know to the public. These health risks could be based on ingredients or preparation methods that are not used when the same or similar foods are prepared at home. The judge also allowed the plaintiffs to add claims (a' la tobacco smokers) that fast food is "addictive" and that the plaintiffs at least individually consumed it in such amounts that it constituted a health hazard.

Shortly after Judge Sweet issued his order, Congressman Ric Keller (R-Florida) and Senator Mitch McConnell (R-Kentucky) announced that they are introducing bills to prohibit federal lawsuits against restaurants and food manufacturers based on obesity related claims.

Fast Food Wars Start In Earnest

New Newsletter Proves It

There is probably no better measure of when a new public policy issue has arrived then when a trade or legal publisher starts a newsletter that specifically addresses that subject. Case in point: Food Chemical News, a trade publication that we read semi-religiously (at least when they're not piled on Mr. Zackler's desk) has sent us a free inaugural issue of Obesity Policy Report with the headline "FOOD = TOBACCO?" The as yet thin newsletter will apparently track legislative proposals such as nutritional labeling, health warnings, special food taxes, advertising restrictions as well as the embryonic lawsuits which are targeting the fast and "junk" food industries. We expect its girth to grown substantially.

Although even obesity "opponents" acknowledge there are some very great differences between tobacco companies and the fast and snack food industries (after all its still legal for an 8 year old to possess a hamburger and for obvious reasons food may be addictive), they expect to score some hits. And with states running substantial deficits, what better way to raise revenue than to tax the stuff or file a lawsuit seeking recovery of medical expenses to treat obesity related

A few predictions:

1. *Labels on processed food products will be carefully scrutinized for accuracy, as will any "voluntary" nutritional disclosures by fast food chains.*
2. *Some local or state governments will develop a half-baked definition of a fast food restaurant (will it include Lyon's, Denny's, mom & pop diner?) and require them to prominently label politically incorrect food with nutritional WARNINGS. So menus will not only contain the "good for you" heart icon, but they also may have a heart icon with a line through it or maybe just a picture of the Grim Reaper. We'll call this the "Prop 65'ing" of America.*
3. *No advertising to minors; heck, maybe no advertising at all.*
4. *Special taxes on fast food and snack foods such as soft drinks and candy*
5. *There will be a move in Congress to give (or force) the FDA jurisdiction over fast food restaurants and impose nutritional labeling requirements and health warnings. (We're taking bets on how many decades it will take the FDA to write these regulations.) Maybe even health warnings on packaged food products.*
6. *Eric "Fast Food Nation" Slosser will get his own talk show and it won't be on the Food Channel.*

For those of you doing business in California and unapologetically selling un-PC food, we predict a few extra goodies in the legal cookie jar. (If you're apologetically selling it, your (very fatty) goose is <u>really</u> cooked.) First, lawsuits under the state's "one size fits all lawsuits" statute called the Unfair Competition Act (officially known as Business & Professions Code Section 17200) and more legal pain if you have the audacity to defend yourself in the court of public opinion. As discussed in the last edition of Food Law Update, the California Supreme Court decided in <u>Kasky v. Nike</u> that the First Amendment only applies to commercial

Table Scraps™

EU's NAME THAT FOOD SAGA #613—Denmark has sued the European Union ("EU") for the right to sell "feta" labeled cheese that is made in Denmark. As discussed in prior issues of *Food Law Update* the EU has developed a list of hundreds of products whose name is proprietary to a particular region including about 150 cheeses. Greece has contended that "feta" cheese can only be produced in certain regions of Greece and made from special goat and cow's milk that will keep the cheese from turning yellow. The Danes and other European producers make their "feta" cheese by adding a whitening compound. Meanwhile EU negotiators at the WTO have proposed a trade rule that would only allow products produced in a specific regtion to use that region's name.

MANDATORY RECALL BILL INTRODUCED—Senator Tom Harkin (D-Iowa) has introduced a bill to give the FDA and the USDA the power to order mandatory recalls if firms refuse to conduct "voluntary" recalls. Harkin's bill provides for civil penalties of up to $500,000 for violation of a mandatory recall order. The bill would not affect any civil liabilities that firms could have for consumer injuries.

KARSKY GOES TO THE SUPREMES—The United States Supreme Court has agreed to hear an appeal of *Karsky v. Nike* in which, as we reported in *Foodlaw*, Winter 2002, a majority of the California Supreme Court held that alleged misstatements by a company on public policy issues of interest to its operation are actionable under California's ubiquitous Unfair Practices Act. By the way, we also forgot to give the justices of the California Supreme Court credit where credit is due. Voting in favor of plaintiff Karsky's lawsuit were Chief Justice George and Justices Werdegar, Kennard, and the Court's only Democratic appointee Justice Moreno. The dissenters were Justices Chin, Baxter, and Brown. You decide who gets the credit.

NEXT THEY'LL BE FLYING— New EU regulations will go into effect within the next 90 days that will require farmers to put "toys" in pigsties. The regulation, which does not specify any particular object, requires one toy for every 20 pigs. Because there are no pig toys on the market (yet), among the objects being considered by farmers are balls and chains. The regulation was enacted because, according to animal welfare rights activists, bored pigs chew on each other. Now they'll get to fight over who gets to play with the toy.

WHAT'S IN A NAME? INJUNCTION ISSUES AGAINST PRODUCT NAME THAT CONVEYED A FALSE MESSAGE-- A divided United States Court of Appeals in Philadelphia has upheld the issuance of a preliminary injunction in a lawsuit brought by Norvis to bar Johnson & Johnson from marketing its over the counter heartburn medicine as "Mylanta Night Time Strength." Norvis had sued J&J under the federal Lanham Act on the ground that "night time strength" implied that the product had been specially formulated to work at night time, when, in fact, the product's formulation has no such unique characteristic.

Prop 65 Lawsuits Filed Against Big Fries and Big Chains

Will Raw Foods Be the Fast Food of the Future?

As usual California lawyers will continue to use the state's own unique laws to tackle food policy issues as two recent lawsuits based upon Prop 65's notice requirements illustrate.

Saying he doesn't sue "small fries," Raphael Metzger, a Southern California "Prop 65" plaintiff's attorney, has filed an action in Los Angeles Superior Court against Burger King and McDonald's alleging that the firms have to post Prop 65 health warnings in their restaurants because their french fries (like french fries everywhere along with other fried and baked foods) contain acrylamide, a carcinogen. Prop 65 warning notices are required for acrylamide exposures in excess of 0.2 mg., which is far lower than the amount per serving found in many foods. Metzger's suit also includes an Unfair Competition Claim. Industry has responded by noting that Prop 65 has an exception for cooking necessary to render food palatable or kill microorganisms. Plaintiffs Prop 65 attorneys are now stating that Metzger's lawsuit might push the envelope on federal legislation to preempt Prop 65 labeling of processed food products. Talk about a possible self-inflicted wound.

Meanwhile, the Contaminants and Natural Toxicants Subcommittee of the FDA's Food Advisory Committee recently met to assess the safety of acrylamide. At the meeting the FDA estimated that there is a 500 fold safety factor for current acrylamide exposure and a Swedish study concluded that there is no link between acrylamides and cancer.

California Attorney General Bill Lockyer has filed Prop 65 lawsuits against 5 supermarket chains claiming that they violated the act by not posting warning notices that fresh tuna, swordfish and shark contain high levels of mercury. The California Grocers Association responded that the organization is working with the AG's office on a proposed notice. It

Ask Allan *(cont'd from pg. 8)*

What's significant about the development of strict liability? Well, first of all it means that no matter how careful you are, if you sell an adulterated product that injures a consumer, you are liable for the consumer's damages. In other words, all of the risk of product injury has been shifted to the processor and the processor's insurer. For the plaintiff's attorney it makes proving the case much easier. The attorney doesn't need to prove the processor's state of mind or whether the processor complied with some sort of standard. Most product liability cases concern whether the product caused the injury. In most cases this is probably obvious, but in some it could be an evidentiary puzzle such as the whether administering of a particular drug caused a medical complication.

There are limits on who is subject to the rule of strict liability. Generally service providers such as doctors, accountants, engineers, attorneys, restaurants, mechanics etc. are not subject to strict liability. Of course, they can still be liable for negligence as well as intentional or reckless misconduct. Also this rule does not cover non-consumer commodities such as industrial chemicals unless they are used to make consumer products, and the injured person must be suing as a consumer of the subject product and not in some other capacity (e.g. a victim of a toxic tort caused by the chemical plant down the street).

One final note. The concept of strict liability is also ubiquitous in the regulatory area although regulators may take into account your degree of culpability is assessing any penalties.

What recall powers do the FDA and USDA have?

With the exception of infant formula, technically neither agency has the legal power to require a food distributor or processor to recall product that is either adulterated or mislabeled. That doesn't mean either agency is powerless, but the reality is a little complicated.

First, we need to understand what a "recall" is. A recall means the *withdrawal* from the market place by a processor or distributor of a food, drug or cosmetic. Recalls are usually done because products either does not or is suspected of not complying with federal law. From time-to-time firms may remove the products from channels of distribution that do not comply with the firm's own QC requirements, but are compliant with the law. These removals are usually referred to as "market withdrawals."

Both the USDA and the FDA do have the power to seek injunctions against firms who ship products that fail to comply with federal law. These injunctions essentially prohibit the firms from shipping or selling adulterated or mislabeled product and can allow the agency to seize the product. Unfortunately for the agencies, once a product is in the market place, absent voluntary compliance, the agencies must seek separate injunctions against each firm (e.g. wholesaler, retailer) that has inventories of the subject product. Just locating these firms could be a major task. However, absent contempt of an order, the agencies cannot require the firms to remove the subject product that is already in the market place.

The FDA has adopted guidelines concerning "voluntary" recalls. The policy categorizes recalls into three categories: Class I for products that might result in serious adverse health consequences or death; Class II for products that may cause non-serious, temporary adverse health effects or have a remote possibility of adverse health consequences; Class III for products not likely to have adverse health consequences. The guidelines discuss in detail recall strategies, notification of FDA, communications to facilitate the recall, and public notification. Both the FDA and the USDA have also created detailed documentation for use in recalls.

So why do firms engage in recalls if they don't have to do so? First, it's the right thing to do. No one wants to injure consumers. Legally, if the firm does not initiate a recall and knows or has reasons to know that a product is adulterated or mislabeled, then it could be liable for punitive as well as actual damages. Second, while a recall is probably never good PR, the failure to do a recall could be even worse PR.

If you have questions or concerns about the need for a

David Liou Joins Zackler & Associates

When you call Zackler & Associates, you may hear a new voice on the line.

David Liou recently joined Zackler & Associates as a legal assistant. Prior to joining our firm, he interned at American Express Financial Advisors where he researched and prepared financial plans to present to clients. David also interned at JL Graphic Design as a web/graphics designer where he developed many of his web design skills which he hopes to utilize at Zackler & Associates.

David has also worked as an administrative assistant at The O'Brien Group, a real estate development firm. He played a vital role in revamping the firm organization of accounting, construction, and insurance files. Among other responsibilities, he also served as the in-house tech support for any technology related problems.

David moved to the Bay Area from Philadelphia in 2000. He is currently a junior at the University of California, Berkeley. He is majoring in Legal Studies and intends on going to law school following graduation.

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The information in *Food & Marketing Law Update* is general in nature and not intended to be relied upon as legal advise. Zackler & Associates will be pleased to privately discuss with you in greater detail the information in this newsletter including its application to your specific business needs. Of course, we welcome your comments and suggestions.

Food & Marketing Law Update

Ask Allan

In connection with consumer complaints about products I've heard the term "products liability" and "strict liability" used. What's the difference and how does it affect my business?

These terms refer to two of the most the most significant common law (i.e. judge made law) developments of the 20th Century. The term product liability refers to the liability of a manufacturer of a product sold to consumers for injuries caused by that product. At the beginning of the last century manufacturers were not liable to consumers for defectively made or inadequately labeled products because consumers lacked "privity of contract" with the manufacturer. Starting in 1918 state courts began dumping the privity requirement and allowing injured consumers to sue manufacturers.

The second development started about 40 years ago when manufacturers of consumer products were made strictly liable for any injuries that their products cause a consumer. In order to understand the significance of strict liability we need to review four types or degrees of civil legal culpability that a manufacturer can have to a consumer. The first type is intentional misconduct. For example, a food processor sells a product that the processor *knows* is adulterated. The second type is called recklessness. (The law school example of recklessness is firing a gun into a crowd not knowing for sure whether the bullet will hit anyone.) In this case a food processor sells a product which the processor believes may be adulterated but does not know this for a fact. In essence the processor is shifting a known risk to its customers. The third type is negligence. The processor believes that its products are wholesome, but it fails to adhere to an industry or regulatory standard when it makes the products and consequently sells an adulterated product. The fourth type is strict liability. In this case not only does the processor believe that its products are wholesome, but it has conformed to industry and regulatory standards when it made the products. Nevertheless, the products turn out to be adulterated.

Ask Allan *(Cont'd on pg. 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