ZACKLER & ASSOCIATES

Food & Marketing Law Update

Volume 18, Issue 2, Summer 2004

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

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TRADEMARKS! TRADEMARKS!

How to Use Them and How to Lose Them

Two recent developments illustrate certain basic trademark principals: brand identification and losing your trademark rights.

The first development is the aborted changes in the National Organic Program ("NOP") guidelines that were issued this April by the NOP program manager who is an employee of USDA. The withdrawn guidelines, which were issued as "clarifications" of existing NOP regulations would have allowed the use on organic crops of pesticides that may contain prohibited ingredients, identification of fish as organic although no organic standards have been developed for fish, the use of non-organic fish meal in organic livestock feed, and allowed dairy cattle to be treated with drugs without removing them from organic dairy herds. We're not going to comment on this change as a matter of science (either food or the political kind) or the legal merits of USDA's action. Rather the controversy illustrates the use of trademarks by NGO's, particularly trade associations, to police the market place.

The word "organic," being a generic term, cannot be trademarked. But what if years ago the then members of the incipient organic industry had gotten together to set up a standard setting board, such as a non-profit corporation, which would have defined organic standards and credentialed organic certifiers? What if this board had developed a trademarkable logo (as opposed to the less than eye catching USDA seal) to be used in the labeling and advertising of products that meet the board's organic requirements and communicated the meaning of this logo to the consuming public? Well maybe today such a seal of approval would have as much recognition as among consumers of organic products as other famous trademarks such as IBM®, Coca-Cola® or McDonald's®.

The creation of private standard setting organizations with significant public recognition is not at all unusual whether it's Good Housekeeping®, UL®, the mark of Underwriters Laboratory, Realtor®., the mark of the National Association of Realtors, or CFP®, the mark of the Certified Financial Planner Board of Standards, Inc. These organizations use their word and/or design trademarks to identify their members and the persons, organizations or products that comply with their standards. Of course, the advantage of private standard setting is that the organizations

Trademarks *(cont'd on p.3)*

FDA Reopens Comment Period for Nutrient Content & Health Claims

The FDA has published a Federal Register notice for comments concerning proposed changes in the requirements for nutritional and health claims on the labels of food products. This request for comments relates to proposals dating back to 1995 concerning the requirements for health and nutritional claims. The FDA has asked for comments on the following topics.

- FDA regulations currently require that a product contain at least 10% or more of a nutrient's daily reference value (DRV) per serving in order to make the claim that the food is a "good" source of that nutrient (e.g., vitamin A or fiber).

FDA Comment Period Reopened *(cont'd on p.2)*

Zackler & Associates has a New Website!

We have redesigned our website. The new site has many new features and improvements including the Information Center, where you will find many research materials, current and prior issues of Food and Marketing Law Update, as well as useful links for you and your business.

In our Firm Profile section, you can find more information about the attorneys, our areas of practice, and other information.

Please check out **www.foodlaw.com** and let us know what you think.

BIOTERROR UPDATE:
FDA Issues Final Detention Rule

The FDA has issued its final rule pertaining to the detention authority given it under the Bioterrorism Act of 2002. The rule, which is similar to the proposal first put forth by the FDA in 2003, provides:

- FDA can now administratively detain any food for up to 30 days (7 days for perishable food) if an FDA employee has reason to believe that the food presents a threat of a "serious adverse health consequence or death to humans or animals," also called SAHCODHA.

- Any detention order must be approved by an FDA District Director prior to issuance

- The SAHCODHA threat need not be due to an act of terrorism (e.g., undeclared allergens in a food could be the basis for detention).

- Under the Bioterror Act, food includes dietary supplements and food contract substances such as packaging. It does not include meat or poultry products that are subject to the exclusive jurisdiction of the USDA

- The FDA may order the food to be detained on site or at a "secure facility." In either case, while under detention the food cannot be moved for any purpose, including destruction, without FDA authorization.

- Once a detention order is issued, the FDA will have four days to commence a federal court procedure to seize perishable detained food. (When food is detained, it remains the property of the owner. Seizure essentially transfers legal title to the food from the owner to the government.)

- The rules provide for the appeal of a detention order. Appeals notices are filed with FDA District Director and an FDA Regional Director will hear the appeal. Appeals of detention orders for perishable foods must be filed within 2 days and appeals of detention orders for non-perishable foods must be filed within 10 days.

- We anticipate that every time a detention order is issued, FDA inspectors will also ask for production of all tracking records. Based on these records, the FDA may issue additional detention orders to ingredient suppliers and/or customers the food processor or distributor whose products have been detained.

With the issuance of this final rule, we are still waiting for the FDA to issue a "final" or "interim final" rule pertaining to the Act's tracking requirements. The FDA has previously issued "interim final" rules pertaining to the two other sections of the Bioterrorism Act that affect FDA regulation, namely facility registration and import pre-notification

FDA Comment Period Reopened *(cont'd from p.1)*

The FDA is considering two possible exemptions to the 10% requirement. One proposal is to exempt fruit and vegetable product and enriched bread and cereal products. The other proposal would exempt products whose DRV caloric percentage does not exceed the DRV percentage of the nutrients. For example, a food that contains 8% of the DRV for vitamin A per serving could be labeled as a good source of vitamin A if the food's calorie DRV per serving does not exceed 8%.

- FDA regulations currently prohibit the use of health claims on foods that exceed certain levels of "bad" nutrients such as cholesterol or fat. The FDA is considering an alternative of allowing health claim to be made on otherwise disqualified foods if affirmative disclosure statements are also made concerning the "bad" nutrients in the food.

- The use of the word "may" in health claims as an alternative to the use of disclaimers in qualified health claims which state that health properties of a food can be dependant upon other factors such as exercise. The FDA is also seeking comment on elimination of the word "may" from unqualified health claims in order to correctly represent to consumers that the unqualified health claim is based on significant scientific agreement.

- Currently the terminology that can be used to describe a product's nutritional benefits is limited to specific words such as "good source," "high," "little," and "contains." Terms that are not expressly allowed by FDA regulations have to be approved by the FDA through a petition process. The FDA wants to see if the restrictions on the approved terminology can be loosened without creating significant consumer confusion.

- FDA has requested consumer study data pertaining to the use of "abbreviated" health claims. Under the proposal the various qualifiers that now must appear in a health claim could be moved to a separate panel on the label. The FDA has also requested comment on how the use of abbreviated health claims may impact the use of "may" in connection with qualified health claims as discussed above.

The comment period closes on July 6, 2004.

Trademarks *(cont'd from p.1)*

determine their own requirements for membership and make their own rules regarding use of their marks. On the other hand, the USDA's NOP will always be under a cloud of internal or external political pressures.

The second development is a much less philosophical and much less published, especially in FDA/USDA circles. The University of Georgia has discovered that it may no longer own its name. The University of Georgia Foundation, which is estranged from the school's current leadership, registered the mark University of Georgia® with the U.S. Patent & Trademark Office after the school's trademark registration was allowed to expire. (Trademark registrations must be renewed every 10 years, and the Trademark Office does not send out renewal notices to registrants.)

We don't know the circumstances of how the University allowed its registration to lapse. (And, in fact, the University should still have common law rights in its name.) But maybe, someone at the school didn't respond to a letter from trademark counsel reminding them that the registration needed to be renewed. So, the moral of the story is: if you are a trademark client of Zackler & Associates, and we send you a letter requesting your response, you should expeditiously respond or your brand name may no longer enjoy the protection of the Lanham Act.

Is It A Food, A Supplement or A Drug?

It's the Marketing That Counts!

A recent article in The Wall Street Journal discussed how producers of some food products such as cranberry juice, oat meal, walnuts and grass fed beef are taking a page from the pharmaceutical industry and marketing their products directly to doctors to "prescribe" to patients.

This combination of food and medicine brings to mind the fact that the FDA has divided products that can be consumed by the body (orally or intravenously) into three categories: food, dietary supplement and drug. So in 11,708 regulations or less, what's the difference? What the product contains? How the product is made? How it affects the body? Well, the simplified answer is that in many instances a product's FDA classification is based on how you advertise it.

If a product is advertised as having a medicinal effect on the body, then it will likely be classified an OTC or a prescription drug. If a product is advertised as affecting the body's "structure/function," then it's likely to be a dietary supplement. If a product is advertised as "good tasting," "refreshing," or with other adjectives expressing sensory delight, then it's likely to be a food. Of course, as far as Mother Nature is concerned, FDA classifications are meaningless. Whether my product XXXX is classified as a food, dietary supplement or as a drug, its physiological effect on the body will be the same.

This simplified analysis leaves out some very significant reg-

Food, Supplement, or Drug *(cont'd on column 2)*

Food, Supplement, or Drug *(cont'd from column 1)*

ulatory distinctions between these classifications such as the fact that (a) the ingredients in food must be GRAS (but not dietary supplements), (b) any products that contain a substance that FDA has classified as a drug must be sold as a drug (c) drugs (but not food or most dietary supplements) need FDA pre-approval before they go to market and (d) both food and dietary supplements can make certain types of FDA approved health claims. Nevertheless, the question of how you will market your product is often as important as what it is.

We often encounter products that are unwittingly being marketed in a manner that is not consistent with FDA restrictions. Zackler & Associates knows all (well almost all) the FDA's 11,798 regulations and can advise you not only about marketing, but also about product formulation, labeling, nutritional claims, and other issues pertaining to the regulation of your product.

Bankrupt Customer? You May Be Able to Get Paid!

Bankruptcies are not infrequent occurrences in the food and retail industries. For example, the liquidation of the Furr's supermarket chain and the reorganization of Fleming, the big wholesaler. In most cases trade creditors either get nothing or just cents on the dollar. Moreover, bankruptcy trustees have become much more aggressive at asserting preference claims or denying reclamation claims. What's an unsecured creditor, namely you, to do?

Well in most cases there isn't much you can do except keep your eyes out for troubled accounts and think COD. However, distributors of fresh fruits and vegetables are a special case. Thanks to the Perishable Agricultural Commodities Act, known as the PACA, distributors of fresh fruits and vegetables are a special class of creditors who stand almost at the front of the creditor's line right behind those friendly folks at the IRS. In fact, produce vendors stand in front of the secured creditors such as banks! The PACA does this by creating a "trust" in the products sold by the fruit and vegetable vendors. The trust consists either of the products themselves or the payment for the products.

Vendors claiming a preference under the PACA usually do so on the Proof of Claim form filed during the bankruptcy. Keep in mind that recovery under the PACA is limited to fresh fruits and vegetables including frozen and fresh cut varieties. Canned and other types of processed fruit and vegetable products are not covered by the PACA. Furthermore, payment terms cannot exceed 30 days. If a vendor's invoice for lettuce is Net 45, then there will be no PACA preference claim.

There are other technical requirements pertaining to PACA coverage, whether or not bankruptcy is involved. Zackler & Associates can help both produce vendors and buyers review their PACA compliance issues and how to assert their rights under the PACA.

Table Scraps™

BioTech—What It's Really All About

The following is a text of letter that appeared in the *San Francisco Chronicle* concerning the protests at the Biotech Industry Organization's BIO 2004 June conference in San Francisco:

> *The street protests, educational lectures and "greening" efforts of activists this week show the growing opposition as well as alternatives, to using genetic engineering technology to produce the food we all eat. What many in the media and industry fail to understand are the connections between this issue and others, such as war and exploding prison populations. Here it is loud and clear: corporate power.*
>
> *Our world, from our food to our international relations, is being shaped by the profit-driven corporate agenda. These issues are not simply thrown together to make bigger protests. Broadly focused demonstrations reflect the broad scope of corporate domination of our lives.*

Senate Passes Allergen Labeling Bill

The Senate has passed and sent to the House an amendment to the Food & Drug Act which would require the specific identification in the ingredient statements of processed foods of the presence of any of the eight major allergens in the products. The bill would require the source food of any ingredient derive from one of the eight allergens to be listed. For example, "semolina (wheat)," "albumin (egg)," or "whey (milk). Alternatively the ingredient statement could merely state the presence of the allergen (e.g., "contains wheat"). The bill appears to generally codify current FDA policy statements pertaining to the identification of major allergens on food labels.

Low Carb as to What?

While the "low carb" labeling craze appears to be continuing unabated, we did notice a couple of warning letters that the FDA sent concerning the proper use of this otherwise unsanctioned term. The letters, one to Russell Stover Candies and the other to Peak Performance Foods, stated that their respective "low carb" claims were false or misleading because the products had the same amount of carbohydrates per serving as comparable products.

Low Carb, But Bad

KFC has been taken to task by the FTC for advertising its fried chicken as having less fat than a BK Whopper and claiming that the chicken is compatible with a low carbohydrate weight lost program. The FTC noted that the chicken was still loaded with trans fat, sodium, calories and cholesterol and that Atkins and the South Beach low carb diets (neither one of which were specifically mentioned in the ads) don't endorse the consumption of breaded fried food.

Where was the FDA? Well, restaurants are not subject to FDA regulation. (Note that the FDA has strict rules when foods can make nutritional claims. The FDA also has no rules, as yet, for low carb claims that "everyone" is making.) The real question is where were (or are) the fat plaintiffs' lawyers?

Remember COPPA?

Just about everyone has a website. Several years ago in order to protect the young ones from any mischief that might befall them on the internet, Congress passed the Children's Online Privacy Protection Act or "COPPA," pursuant to which the FTC enacted strict (and, of course, confusing) regulations pertaining to how websites can communicate with kids who are 12 and younger and some costly penalties if you don't comply. Well, as recently reported in the NAD's Do's and Don'ts in Advertising, the FTC has undertaken a slew of enforcement actions including cases against GeoCities, Liberty Financial Companies, Toysmart, Monarch Services, Girls Life, Lisa Frank, American Popcorn Company, Mrs. Fields Cookies, Hershey Foods, and UMG Recordings. What these actions illustrate is how easy it is to run afoul of COPPA.

Creating a new website? Redoing your current one? Better call Zackler & Associates before you get a notice from the FTC.

Watch Out for the Hotdogs—They're Loaded (and We Don't Mean with Fat)

A woman claimed that a Hebrew National hotdog that she purchased at a refreshment stand in an Irvine, California Costco store contained a 9 mm bullet. After biting into the bullet the woman was taken to the hospital after she complained of stomach pains and doctors found that she had ingested another bullet. A check of all the remaining hotdog packages by the Irvine police did not find any additional ammunition. A check of the FDA website does not list any subsequent recall of "loaded" hotdogs.

Registering Domestic & International Trademarks - The Madrid Protocol

The Madrid Protocol is a treaty that represents a new opportunity for U.S. companies to register their trademarks domestically and internationally. As of November 2003, 61 countries joined the Protocol. The Protocol allows you to use a single application to register your marks with the U.S. Patent and Trademark Office ("USPTO") and other designated member countries such as China, Japan, France, and the United Kingdom.

The Protocol has many benefits when filing in other designated member countries. Applicants file a single application in one language instead of multiple applications in various languages. You will no longer need to hire local attorneys in individual countries or pay for translation fees. Also, the single application is assigned a single renewal date as opposed to separate renewal dates for each country.

Nevertheless, there are some drawbacks to utilizing the Protocol process. First, if an application is rejected or a registration is canceled within five years of the international registration date, the mark owner will have to file multiple national applications within three months to maintain your priority for international protection. Secondly, the simplicity of a single application limits an applicant's flexibility in defining the range of products or services that the trademark covers because of different regulations or requirements that may exist in different countries. For example, USPTO regulations may limit a description of goods or services on which a mark will be used, but the USPTO limitation may not apply in other countries that belong to the Protocol.

It is strongly recommended that if you are looking to register trademarks both domestically and internationally you evaluate how your registration strategy might be affected by the Protocol. Zackler & Associates will help you evaluate (a) whether you should use the Protocol when registering a mark internationally or if separate national registrations will be in your best interests; (b) whether a mark you are currently using or intend to use might be free of opposition from a non-domestic trademark registrant; (c) completing the necessary paperwork for filing with the USPTO; and (d) responding to issues raised by the USPTO or other trademark owners. We will work with you to ensure that your trademark will be registered in a timely and cost efficient manner.

Ask Allan *(cont'd from pg. 6)*

See the discussion in the Fall 2003 issue of F&MLU concerning the FDA's new detention authority under the Bioterrorism Rules.) Nevertheless, most processors and distributors will engage in recalls whenever necessary. Also, don't forget that plaintiffs' tort lawyers are not limited by FDA rules.

The FDA has issued guidelines concerning recalls. The guidelines divide recalls into three classes. The most serious is a Class I recall which occurs when there is a reasonable probability that consumption of a food will cause serious adverse

Ask Allan *(cont'd on column 2)*

Ask Allan *(cont'd from column 1)*

health consequences or death to humans or animals. Undeclared allergens are Class I recalls. A Class II recall involves a food that may cause temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences is remote. Finally, a Class III recall involves a food that is not likely to cause adverse health consequences. The guidelines ask that processors and distributors notify the FDA of a recall, and the agency will publish the recall in its Enforcement Report as method of providing public notice. The guidelines also ask that processors provide the FDA with status reports.

There are a number of practical considerations involved with recalls. Most importantly each processor should prepare a recall plan as a part of its standard operating procedures. It is simply too late to write a recall plan when you are in the process of doing a recall. A good recall plan should include:

- A description of the triggering events that will cause the processor to institute a recall and the identification of the person(s) who will make the call
- Line of command in recall.
- Duties for each department and employees within those departments
- Points of contact for internal and external communication.
    - distributors, brokers, retailers
    - public
    - press
    - regulators
- Up-to-date phone and fax numbers, including home numbers, for responsible individuals and alternates.
- Forms for recall communications to distributors, to public, to press.
- Forms for tracking recalled product.
- Accounting procedures

We have seen recall manuals of only a few pages including forms and manuals and others that are over 100 pages. Beyond the basic elements, the manual should be customized to a firm's products, distribution and operating structure. Needless to say, employees should receive training about recalls prior to the occurrence of an event. This is not a situation where you want to do "on-the-job" training.

The success of a recall is basically measured by its ability to get the product off the selves and out of the chain of distribution. For those of you that have had the unfortunate experience of a recall, you know that this is much easier said than done.

Recalls involve a number of complex legal, food science, marketing, public relations, and logistical issues. When you face a potential recall issue contact Zackler & Associates. We have experience in all aspects of recall related matters. We can help you determine if a recall is necessary, what class of recall it should be, how to handle recall logistics, how to communicate internally and externally, and how to deal with regulatory agencies on your behalf. We will also work with you to develop recall policies and strategies that will leave you well prepared should your company ever need to engage in a recall.

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Food & Marketing Law Update

ASK ALLAN

Product recalls are a common occurrence in the food industry. The FDA Website lists about 70 Class I Recalls during a two month period. What are the legal requirements for a product recall?

First, let's distinguish a recall from other types of actions that a food processor or distributor might take to remove its product from distribution. A recall is the removal of a product from a company's chain of distribution because it's believed that the product may adversely affect the health of humans or animals. The adverse health affect may be due to adulteration, mislabeling (e.g. undisclosed allergens in the product) or possible contamination from foreign sources due to improper handling after production.

There are two other non-recall actions that a food processor or distributor might take to remove its product from distribution. One category is a "market withdrawal" which occurs when a food processor or distributor removes from distribution a product because there is a minor (i.e., non-health related) violation of FDA regulations such as an incorrect calorie listing in the Nutrition Facts or which involves no violation (e.g., product that was not properly formulated during production and therefore is unacceptable for taste or other sensory reasons). The other non-recall action is called a "stock recovery." This occurs when the product in issue is still in the processor's or distributor's control such as food stored at a company or public warehouse. A stock recovery could involve product that either presents a risk to human or animal health or product that has a minor or no violation of FDA rules. In other words, a stock recovery could involve product that could be the subject of a recall or alternatively a market withdrawal had the product been in distribution.

Back to recalls. Let's immediately clear up one misconception that is shared by members of the public and most of the media. The FDA has no legal authority to order a recall, except when the product is infant formula, but can "request" a processor to commence a recall if the processor decides not to do so on its own motion. Therefore, recalls are "voluntary." If a processor or distributor declines to recall a product, then the FDA has to convince a U.S. Attorney to file a seizure in federal court. (However, times are a-changing.

Ask Allan *(cont'd on p.5, column 1)*

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