ZACKLER & ASSOCIATES

Food & Marketing Law Update

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

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FDA to Calif. Attorney General: Hands Off Our Label

The Commissioner of Food and Drugs has sent a letter to California Attorney General Bill Lockyer telling the Attorney General that the Federal Food, Drug and Cosmetic Act ("FDCA") preempts a lawsuit that he filed in 2004 against a seafood processor for failing to provide Prop 65 warning notices on its canned tuna stating the tuna contains mercury and mercury compounds. Lockyer has obtained settlement agreements with both retail grocers and restaurant chains to post warning notices concerning mercury in non-processed fish sold in the stores and fish served at the restaurants. What's going on here and what are the implications for our readers who aren't in the canned tuna business?

First, a brief constitutional law primer. The U.S. Constitution gives Congress the power to regulate interstate commerce. Note that Congress is not required to regulate interstate commerce but is given the option to do so. Over the years, and in particular beginning with the New Deal, the federal courts have given increasingly broader scope to the concept of interstate commerce. Now, virtually any activity, no matter how insular, can be subject to federal regulation.

Congress' regulation of interstate commerce comes in two forms-- exclusive and non-exclusive—and it is up to Congress to determine which of these forms it will use. Exclusive means that the Federal Government writes all of the rules and regulations pertaining to a subject. The states can't create different standards. Non-exclusive means that the Federal Government will set minimum standards and the states can impose higher standards. For example, California (and now some other states) have adopted automobile emissions standards that are much stricter than the federal standards. Another recent example

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ALLAN ZACKLER PRESENTS TO WORLD OBESITY & WEIGHT LOSS CONGRESS, WASHINGTON, D.C.

Allan Zackler made a presentation entitled "The Brave New World of Obesity: Can You Still Promote Your Products Without Risking Litigation or Regulatory Action?" at the just concluded World Obesity & Weight Loss Conference in Washington D.C. In addition to Allan's presentation, the two day conference included presentations and speeches by representatives of the FDA, FTC and other federal agencies, pharmaceutical, dietary supplement, and food manufacturers, marketing organizations, financial institutions, and R&D companies.

Allan's presentation focused on the current regulatory requirements for making nutritional and health claims about food products and dietary supplements, how the traditional federal regulatory model is evolving into a much more diversified and less uniform system of state and even local regulation, and how private legal action may shape the product formulation and marketing landscape in the future. Using some brief case studies, Allan looked at different marketing strategies that could succeed or fail in the currently evolving regulatory environment.

This PowerPoint presentation is intended for all segments of the food and dietary supplement industries. Please contact us if you would like to arrange for a private showing of Allan's presentation in which he will focus on the issues most pertinent to your business.

Also, see the article on page 4 of this issue for a description of three other presentations that we have available.

Your Ingredients Aren't GRAS - Maybe They're EAFUS?

As our clients in the food business know, or should know, GRAS is the acronym for Generally Recognized As Safe. When an ingredient has an FDA GRAS affirmation, it can used in a food without any peril that the FDA might find the food to be adulterated or unsafe. More commonly, this is called a "safe harbor." Some GRAS affirmations allow unrestricted use of an ingredient and others may limit an ingredient's use to certain foods and/or certain amounts.

An ingredient does not have to be FDA GRAS affirmed to be used in food. It can be self-affirmed, meaning that the company using the ingredient in its product has sufficient evidence to demonstrate that its use of the ingredient is safe.

EAFUS is a list of about 3,000 ingredients maintained by the FDA and stands for Everything Added to Food in the United States. The list can be seen at http://www.cfsan.fda.gov/~dms/eafus.html. When you peruse the list you'll notice that some of the ingredients have cross-references to the Code of Federal Regulations ("CFR"). These are the ingredients that have one or more FDA GRAS affirmations. The other ingredients do not have a cross-reference to the CFR's. These ingredients do not have an FDA GRAS affirmation. However, you can still be use them in your food products if you have sufficient evidence to demonstrate that your use of the ingredient does not present a danger to the public health. But, you do this at your own risk. There is no safe harbor to protect you from the FDA or those ever pesky public interest groups and plaintiffs' lawyers.

A final note on FDA GRAS affirmed ingredients. In some cases, when the FDA imposes a restriction on the use of a GRAS affirmed ingredient, the limitation is an absolute restriction and not merely a safe harbor limitation. If the GRAS affirmation contains an absolute restriction and you violate it, then your food product will be adulterated.

Trademark Protection at the Border

Are you concerned about imported products that are illegally using your federally registered "®" trademark? If so, you can buy yourself some cheap protection from the U.S. Customs & Border Protection ("CBP"). CBP has an intellectual property rights protection program under which you can register your registered trademark for a nominal fee on a CBP data base. The registration form includes information concerning persons who are authorized to ship products into the U.S. that are marked with your trademark. CBP will seize any unauthorized shipments of goods that are marked with your trademark.

For more information, contact Steve or Allan

FDA--Hands Off *(cont'd from p.1)*

of non-exclusive regulation is the banning by several states of the sale of products containing Ephedrine before the FDA took action to do so.

Sometimes it's not obvious whether Congress adopted an exclusive or non-exclusive standard in which case the courts will be called in to referee.

Getting back to the Commissioner's letter, it appears to reinterpret a provision in the Nutritional Labeling and Education Action of 1990 ("NLEA") which is part of the FDCA. The Commissioner's letter takes the position that such warnings are not acceptable if they are contrary to FDA policies. Specifically, the Commissioner said that the use of Prop 65 warnings on tuna labels would frustrate FDA policies concerning the nutritional benefits of tuna (e.g. omega-3 fatty acids) and the FDA's program to provide off label information to consumers about mercury in tuna and other seafood. Furthermore, a Prop 65 warning would result in the product being misbranded because such a warning would not provide adequate information to place the warning in context. As of publication of Food & Marketing Law Update, Attorney General Lockyer had not yet responded to the Commissioner's letter.

The public policy implications of the FDA's action and whether the Commissioner's or the Attorney General's position (assuming he doesn't agree with the Commissioner), are significant to everyone in the food and supplement industry. One theme that we have extensively commented upon in presentations to industry groups has been the rise of "federalism" by which we mean regulatory actions taken at the state level that affect the formulation, labeling and marketing of food and dietary supplements. Assuming that the Commissioner prevails, can the Attorney General require retail grocery stores to post Prop 65 warning notices at locations were canned tuna is sold?

Neither store shelves nor restaurant menus are subject to FDA jurisdiction, and as noted above, the Attorney General has already taken action to require warning notices at meat counters for certain unprocessed fish products and on restaurant menus. Can the FDA successfully argue that such off label warnings will frustrate its regulatory policies, and if so, will the courts extend the FDA's exclusive jurisdiction beyond a food's label? In the age of obesity with some states becoming much more activist regarding the regulation of food, where and how these lines are drawn may be critical to the industry, particularly if national standards become subject to as many as 50 different state standards.

Meanwhile, undeterred by the FDA letter, Attorney General Lockyer has filed another Prop. 65 lawsuit against several fast food chains, snack food manufacturers and food processors for failure to label their processed potato products as containing acrylamide.

OBESITY NEWS

ANOTHER MCDONALDS' CASE

As probably most of our food and dietary supplement clients know, there has been a federal class action case pending in New York City against McDonald's called Pelman in which some plaintiffs alleged that they ate McDonald's food, got fat, and McDonald's marketing practices violate New York's Unfair Practices Act, which closely resembles California's Unfair Practices Act. The off-again, on-again lawsuit is now on again after the federal Second Circuit Court of Appeals reversed the trial court judge's dismissal of the action. The case will now proceed on the issue of whether McDonald's falsely advertised its food to be healthful.

Well, there has also been a much less publicized lawsuit pending in Marin Country California. According to a settlement notice that was recently published in Parent's magazine, the lawsuit related to claims of misleading advertising by McDonald's based upon its failure to remove trans fatty acids from the cooking process for some of its products as it previously publicly promised to do.

According to the settlement notice, which doesn't identify the name of the case or the attorneys for either the plaintiff (no, it wasn't CA Attorney General Bill Lockyer) or McDonald's:

1. Although it's a California state court action, the settlement applies nationally.
2. The total monetary amount of the settlement is $10.5 million, which includes a $7 million donation to the American Heart Association, $1.5 to notify consumers that some products are still being made with trans fat containing cooking oils, and $2 million for legal fees and related expenses. (Sorry, no free food coupons or the like for the consumers, i.e. all McDonald's customers, who bought the food made with the trans fat containing cooking oils.)
3. When the settlement is approved McDonald's will be immune from further legal action pertaining to this matter, except for those class members who opt out, all eight of them.

It's an unusual settlement since the bulk of the moneys go to a charity not involved in the litigation. The rest goes to plaintiffs' attorney (of course) and not to the consuming public.

CEREAL COMPANIES SUED OVER "LOW SUGAR" CLAIM

Obesity related lawsuits aren't limited to fast food chains. A San Diego mother named Jennifer Hardee has filed a class action lawsuit against Kraft, Kellogg and General Mills in which she claims that the companies' marketing of their "low sugar" cereals is misleading because the sugar was replaced with other carbohydrates which did not change the products' nutritional profiles. A similar lawsuit has been filed against Kellogg in Montreal.

We don't yet have any additional information concerning these lawsuits, and it's way too early to tell how they will progress. But, if we were plaintiffs' lawyers we'd hope to find the following memo or email written by a marketing person in the files of one of the defendant's:

> "Although the low sugar formulation of the products won't change their nutritional profiles, we won't have any legal problems as long as keep our mouths shut and don't say anything otherwise. If consumers think that "low sugar" means "better," well, that's their problem."

Of course, if you and your employees have attended our seminar on best legal practices (see page 4 of this issue), there would be nothing for the plaintiff's attorneys to find.

Is a Trans Fat Ban Coming?

We were going to headline this article the "Journal of Trans Fat" but it sounded too much like some boring, unfathomable technical piece. We're never boring here and hope not to be unfathomable.

As you all know, Topic A in food regulatory policy has been obesity and its underlying nutritional issues. When Allan Zackler addressed the Northern California Institute of Food Technologists last May he discussed some alternative regulatory approaches, one of which would be to ban certain "bad" food ingredients. If you attended that meeting, you'll know that Allan didn't think that bans on particular types of foods or ingredients would be practical. Well, he may still be right, but it looks like a ban may be coming. Case in point: trans fat has no nutritional value.

All packaged food products will have to be trans fat labeled in their Nutrition Facts panel by January 1, 2006. (This rule also applies to the Supplement Facts panel.) In order to avoid the stigma of trans fat, food processors are busily reformulating their products. We've characterized this labeling requirement as a "back handed ban," although we understand that some products haven't, as yet, been successfully reformulated and will have to carry the dreaded disclosure.

Of course, the restaurant industry isn't subject to FDA jurisdiction. It's regulated by state and local authorities. Now the New York City Health Department has asked the restaurants in the City to "voluntarily" stop serving food that contains trans fat. Will voluntary become "mandatory?" And if local or state authorities do successfully ban trans fat, will the FDA be forced to follow suit? If the FDA does follow suit, how would it do so? Tran fat isn't an ingredient. It's a nutrient in a bunch of ingredients. Will all of these ingredients be banned or they be severely restricted?

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Zackler & Associates
Provides the Following Legal Services:

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- New Product Development/Regulatory Concerns
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- Drug, Cosmetic & Medical Device Issues
- Energy Issues
- Distribution Law

Presentations from Zackler & Associates

We have developed in person presentations on general legal topics that may be of interest to our clients in both the food industry and our clients who are in other business sectors. These are Power Point presentations that have designed to background business owners and managers and their key employees on key legal topics in a non-technical manner.

Right now our library includes the following topics:

BEST LEGAL PRACTICES: The basics that every business person needs to know in starting and operating their business in order to avoid or limit legal problems and what to do or not do if a legal entanglement becomes unavoidable. The emphasis will be on proactive things you can do to ensure that your time and money is invested in your business and not in resolving legal problems.

LEGAL AND REGULATORY ASPECTS OF THE MARKETING OF FOOD AND DIETARY SUPPLEMENTS: Are you taking legal risks in marketing your products that you don't even know about? Are you failing to make all of the FDA sanctioned claims about the nutritional or health benefits of your product? Are you using or do you want to use marketing techniques that are in a legal gray area? We'll look at the usual regulatory suspects, the FDA, USDA and the FTC as well other less likely, but equally potent sources of legal limitations to the marketing of your products. We'll then review the current FDA regulations and enforcement policies regarding statutory and "qualified" health claims and nutrition content claims and comment on how you can "push the envelope" without going over a legal deep end.

OBESITY AND THE MARKETING OF FOODS AND DIETARY SUPPLEMENTS: The great national debate over obesity and related nutritional topics is only going to get more intense. This presentation looks at the current parameters of this debate from a regulatory point of view and will provide you with a road map of who might regulate your products and how they might regulate it. We'll look at how you can market "good" products and what you will need to watch for if you are marketing a "bad" product.

All of these presentations can be customized to your specific business. In addition, we can work with you to develop presentations on other topics.

For more information about the presentations or to schedule one, please contact Allan or Steve.