

Food & Marketing Law Update

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New Tools to Help Consumers Use the Nutrition Facts Label

The Department of Health and Human Services (HHS) and the Center for Food Safety and Applied Nutrition (CFSAN) have announced the availability of two new learning tools to help consumers use the Nutrition Facts label to choose nutritious foods and achieve healthy weight management: Make Your Calories Count, a Web-based learning program; and a new Nutrition Facts Label brochure.

Make Your Calories Count is an interactive online learning program that is also available in a downloadable format. It is designed to help consumers understand and use the Nutrition Facts label to plan a healthy diet while managing calorie intake. The program guide

features an animated character called "Label-man" who leads the viewer through a series of exercises on the food label. The program includes exercises to help consumers explore the relationship between serving sizes and calories, while they learn how to limit certain nutrients and get enough of others. For simplicity, the program presents two nutrients that should be limited (saturated fat and sodium) and two nutrients that should be consumed in adequate amounts (fiber and calcium).

Consumers can use the Nutrition Facts label to take control of their caloric intake and weight and to make healthy food choices, if they know how. This program will show

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USDA Conundrum: What is Organic Fish?

Proposed USDA guidelines which would allow certain farm fish to be called "organic" have become a source of controversy--even amongst the groups who were thought to be its biggest supporters. In its proposal, the USDA describes an organic fish as one that eats either a) an entirely organic diet or b) a nonorganic fish meal from sustainable fisheries or c) nonorganic fish while the fish farm is in transition to organic fish meal. To the dismay of fishermen, the proposal essentially disqualifies wild-caught fish from the "organic" label because their living conditions and diet are not controlled. Environmentalists, on the other hand, argue that farm-raised fish cannot be labeled "organic" because they live in cramped conditions which may pollute the water. Meanwhile, many who favor the USDA's designation of "organic" for farmed fish cannot agree on the types of fish which

should be included. There is broad agreement that the organic label is no problem for fish that are primarily vegetarians, like catfish and tilapia, because organic feed is available. Carnivores like salmon, however, are a different matter because they eat other fish which are not labeled organic. The USDA proposal baffles many connected with the fishing industry since wild fish living in pristine waters are favored by fish lovers. "If you can't call a wild Alaska salmon true and organic," asked Alaskan Senator Lisa Murkowski, "what can you call organic?" At stake is more than the right to label fish "organic": in 2005, sales for organic products reached \$13.8 billion. Those who make a living catching and selling wild fish worry that the "organic" label will give fish farmers a huge advantage in the battle for the consumer's dollar. ■

Secret for the “French Paradox” Discovered?

It's red wine, of course...at least, if you're a mouse.

With its rich cheeses, buttery pastry, and sauces laden with butter and cream, French cuisine could well qualify as one of the most artery-clogging on the planet. And yet, despite enjoying a diet much higher in fat than that of the typical American, the French suffer far less heart disease—the so-called “French Paradox”. Researchers have long suspected that the secret lay in red wine.

A study by the Harvard Medical School and the National Institute on Aging has recently zeroed in on resveratrol, an ingredient found in the skin of grapes and in red wine, as the possible key. In the study, it was discovered that obese mice living on a high-fat diet lived longer, healthier lives—without dieting—by adding huge doses of red wine extract to their diet. Obesity-related deaths dropped 31 percent for overweight mice on the supplement, compared to fat mice that got no treatment, and there were lower rates of diabetes and liver problems.

According to the study, the mice that got the supplement also lived longer than expected. Furthermore, the organs of the obese mice treated with resveratrol looked normal and healthy. Preliminary work shows that resveratrol has promise in extending the lives of the normal mice as well. According to Dr. David Sinclair of Harvard Medical School, leading author of the study, “If we're right about this, it would mean that you could have the benefit of restricting calories without having to feel hungry. It's the Holy Grail of aging research.” A caution, though – these are mice; there is no guarantee that this will work on humans. ■

New Health Claim: Low Fat Diets and the Risk of Heart Disease

The FDA has authorized the following new health claim regarding the consumption of saturated fat, trans fat, and cholesterol and the reduced risk of heart disease.

“Diets low in saturated fat and cholesterol, and as low as possible in trans fat, may reduce the risk of heart disease.”

To qualify for the health claim, the food must be (a) “low in saturated fat” and “low cholesterol”, (b) contain less than 0.5 g of trans fat per RACC or meet any definition of “low trans fat” that FDA may establish in the future, (c) contain less than 6.5 g of total fat per RACC, and (d) comply with all the general requirements for health claims set forth in 21 CFR §101.14. The health claim went into effect on November 15, 2006. ■

Fish Oil Linked to Lower Alzheimer's Risk

Scientists have found that people with the highest blood levels of an omega-3 fatty acid called docosahexaenoic, or DHA, were about half as likely to develop dementia as those with lower levels. DHA is one of several omega-3 fatty acids found in fatty fish and in some meats (in smaller amounts). The substance is also found in fish oil supplements. According to a study published in the November issue of *The Archives of Neurology*, people who ate two or more servings of fish a week reduced their risk for dementia by 39 percent. The finding that DHA alone reduces risk, the authors write, is consistent with earlier data showing high levels of DHA in healthy brain tissue and low levels of DHA in the brains of people with Alzheimer's. The authors of the study caution that the study doesn't prove that eating fish oil prevents dementia. Also eating fish is not a guarantee of having high levels of DHA. The kind of fish consumed is important. Fatty fish is best and frying causes the DHA to deteriorate. The authors also point out that there are no published human studies of the effects of omega-3 fatty acid supplements. Although the FDA doesn't endorse DHA or fish oil capsule consumption, it recognizes that doses of up to 3 grams a day of fish oil is generally safe. High intakes of fish oil can cause excessive bleeding in some people. ■

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2008. The company estimates that the resultant reduction of trans fat levels in its food will be 0.5 gram per serving, a level that would qualify it for free of trans fat in the USA. According to McDonald's CEO, the fast-food chain is making “good progress” towards developing a healthier oil for French fries in its US restaurants; however, he wouldn't give a timetable for the switch.

Finally, on December 5, 2006 the New York City Board of Health voted to ban the use of trans fats in the city's restaurants. According to the ban, restaurants will have until July 2007 to replace their cooking oils and shortenings; by July 2008 they must eliminate trans fats altogether. The ban contains some exceptions; for instance, it would allow restaurants to serve foods containing trans fats which come in the manufacturer's original packaging. While many applaud NYC's trans fat ban, there have been complaints in the restaurant industry, particularly from national chains, that the Board's timeline is unrealistic and that the ban itself is burdensome and unnecessary. Furthermore, the American Heart Association cautions that restaurants may resort to using unhealthy replacements for trans fat such as palm oil in an effort to meet the deadline. Nevertheless, a city-wide ban on trans fats appear to be the wave of the future: Chicago, for example, is also considering a trans fats ban. ■

Updated Labeling Guidelines for Fruit, Vegetables and Fish

In accordance with the NLEA, the FDA has amended the voluntary nutrition labeling regulations for the 20 most frequently consumed raw fruits, vegetables and fish in the USA by updating their names and nutrition labeling values and by clarifying the guidelines for the voluntary nutrition labeling of these foods. Specifically, the new guidelines state that when a retailer provides nutrition labeling for more than one raw fruit or vegetable on a sign, poster, brochure, notebook or leaflet, the listings for saturated fat, trans fat, and cholesterol may be omitted if a footnote is included that says most fruits and vegetables contain negligible amounts of these ingredients, with the exception of avocados, which contain 0.5 grams of saturated fat per ounce. When retailers provide nutrition labeling information for more than one raw fish on signs, posters, brochures, notebooks, or leaflets, the listing for trans fat, dietary fiber and sugars may be omitted if a footnote reads "Fish provide negligible amounts of trans fat, dietary fiber, and sugars." ■

Final Rule on Use of Cattle Materials in Food & Cosmetics: Record Keeping Requirements

In an effort to protect consumers from bovine spongiform encephalopathy (BSE), otherwise known as "Mad Cow Disease", the FDA has issued a final rule regarding the use of "prohibited cattle materials" in human food and cosmetics. Because there are no reliable tests for the BSE agent itself, FDA has concluded that it needs to rely on the records of manufacturers and processors to demonstrate that FDA-regulated products are free from "prohibited cattle material." Therefore, the rule requires manufacturers and processors of human foods and cosmetic products that are manufactured from, processed with, or otherwise contain material from cattle to establish and maintain records sufficient to demonstrate that such products are not manufactured from, processed with, or do not otherwise contain "prohibited cattle materials." Such records must be available to FDA for inspection and copying and must be retained for two years after the date they were created. This recordkeeping requirement applies to manufacturers and processors of finished products, food ingredients, food additives, and dietary ingredients for use in dietary supplements. The final rule also imposes new requirements with respect to the importation of human foods and cosmetics that are manufactured from, processed with, or otherwise contain cattle material.

The final rule will become effective on 01/27/2007. ■

Presenting the New Qualified Health Claim: Canola Oil

The FDA has authorized a qualified health claim relating to the consumption of unsaturated fatty acids from canola oil and its connection to a reduced risk of coronary heart disease. Conventional foods eligible to bear the qualified health claim are limited to canola oil and certain canola oil products, specifically vegetable oil spread, dressings for salads, shortenings, and canola oil-containing foods. The qualified health claim provides as follows:

"Limited and not conclusive scientific evidence suggests that eating about 1 ½ tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of canola oil."

If you would like further information regarding this or any other qualified health claim, please contact Allan Zackler. ■

Practice Note: Consider having a legal preventative check-up. Zackler & Associates can review your contracts, corporate documentaion and regulatory issues to help spot issues before they become problems.

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consumers how, in part, by explaining what serving sizes, percentages, and daily values mean and how to use them. This program is available for online use and in a downloadable format at www.cfsan.fda.gov/label-man. FDA is making available a new downloadable Nutrition Facts Label brochure that is targeted for use by consumers. The brochure can also be used by health professionals to teach people how to make healthier food choices. The brochure describes how consumers can use the Nutrition Facts label as they shop and plan meals. The brochure includes information that will help consumers understand the relationship between calories and serving size, which may help them use the label to manage their intake of calories. This brochure is available at <http://www.cfsan.fda.gov/~dms/lab-gen.html>.

These new learning tools are part of a commitment by HHS and FDA to help reduce the number of overweight persons and obesity in America. ■

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Zackler & Associates

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- Antitrust & Corporate Compliance Review
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The War on Trans Fats

There have been a series of developments in the ongoing battle to curb trans fats:

In August 2006, Wendy's, the nation's No. 3 fast-food chain, switched to a new blend of corn and soy oil for french fries and breaded chicken items in its US and Canadian restaurants. The switch makes Wendy's the first national hamburger chain to use nonhydrogenated oil. According to Wendy's, the move reduces the trans fat in its french fries to just zero to 0.5 grams, depending on serving size, while all breaded chicken products have been reduced to zero grams of trans fat.

In October, Kentucky Fried Chicken announced that it is planning to switch to trans fat free cooking oil in all of its US restaurants. The conversion is expected to be completed by April 2007. While trans fat will be eliminated from

chicken and other fried products, it will remain in biscuits and other menu items because no good alternative has been found. Officials at KFC, a subsidiary of Yum Brands, said the change in cooking oil will have no impact on the taste of its food. In June 2006, the Center for Science in the Public Interest had sued KFC, seeking to force the restaurant chain to quit using partially hydrogenated oils. The group withdrew its suit after KFC's announcement. The Center noted that KFC's announcement could put pressure on other fast food restaurants to eliminate trans fats from cooking oil. The suit is still being pursued by a plaintiff's law firm.

In November, McDonald's Corporation announced that it would begin to use cooking oil with lower levels of trans fat in its European restaurants by mid-

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The information in Food & Marketing Law Update is general in nature and not intended to be relied upon as legal advice. 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.

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