VENABLE LLP

Venable's Regulatory Report on Consumer Products

FOOD, DIETARY SUPPLEMENTS, COSMETICS & OTC DRUGS JULY 2006

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Selling Youth

If you survey the consumer products industry you will see that anti-aging products—those promising continued youth or even turning back the hands of time—are on the rise. In the past, anti-aging products were typically limited to cosmetic products. We are all familiar with brands such as Oil of Olay, Neutrogena and Ponds promising to maintain youth or shave years off. Today, however, the anti-aging products have found new outlets in the form of dietary supplements and foods. Large companies such as Nature Made and Solgar are selling supplements formulated specifically to combat wrinkles, cellulite, memory loss and other conditions associated with aging. Following in the footsteps of its cosmetic predecessors, foods are now beginning to offer new and innovative ways to combat aging.

Conventional Foods and Dietary Supplements

In the area of conventional foods there are a number of juices being introduced into the marketplace that are marketed as lifestyle beverages and that are promising to maintain and/or restore youth. For example, AlphaGenics, Inc., a Rockville Maryland firm specializing in NutriGenomics, is developing a new line of personalized lifestyle beverages that match a person's genetic chemistry. The beverages are to be marketed under the name JeneJuice and contain ingredients that are adjusted based on how the ingredients interact with selected genes. According to AlphaGenics, adjusting food ingredients to match a person's genetic chemistry, physiology and metabolism provides the ultimate personalized consumer experience. Genetic chemistry personalization delivers what consumers want most today: to perform better physically, to control their weight, to look and feel younger, and to be sharper mentally. The product is planned for roll-out in the U.S. in late fall 2006. Other examples of youth promoting juices are pomegranate and Acai juices. Both are marketed as containing high amounts of antioxidants that promote anti-aging.

In the dietary supplement industry, there has been a distinct increase in supplements specifically designed to promote anti-aging. Products such as New Chapter's Anti-Aging formula promises restored energy

and a youthful appearance. Murad's Youth Builder Supplement promises to reduce visible lines and wrinkles and increase skin elasticity after four weeks. The formula is patented and is marketed as supplying essential amino acids, vitamins and minerals that aid in healthy collagen formation, helping the body to defy the signs of aging associated with the thinning of the collagen layer. Nutraceuticals markets its MSM Plus as a therapeutic blend of 20% MSM (an organic sulfur supplement), vitamin C, aloe vera, vitamin E, essential oils and herbal extracts that rejuvenate the skin's natural ability to protect itself against wrinkles and dryness. Vitalfan Antichute markets its products for thin hair to combat various imbalances of the scalp, hair, and skin. The formula includes a dry extract of Cardamine, amino acids to promote keratin production and stimulates scalp circulation. Other supplement products contain collagen, human growth hormone precursors and little known ingredients such as red deer velvet promise to reduce wrinkles, clear age spots, combat cellulite, prevent hair loss, improve vision, mental clarity, improve skin elasticity and suppleness and restore natural color to hair.

Now that conventional foods and dietary supplements are promising continued youth, the question is: What position have regulators such as FDA and FTC taken in regards to such claims?

FDA and FTC

While sales in this area appear to be on the rise, regulators such as FDA and FTC are skeptical about anti-aging products and anti-aging claims. Both FDA and FTC question whether conventional foods, dietary supplements or cosmetics are really a fountain of youth. In this area of marketing, careful drafting of claims and the product category are important to how anti-aging claims will be regulated. It is important to note that neither FDA nor FTC object to anti-aging claims. FDA is concerned whether certain claims could cause the product to be transformed into an unapproved new drug subject to FDA's drug approval process. FTC, on the other hand, questions whether the scientific evidence in support of the claims demonstrate that the products can deliver the promises of restored and/or maintaining youth.

FDA

To date, FDA does not have a hard and fast rule against using "anti-aging" claims on the labels and in the labeling of conventional foods or dietary supplements. Using claims such as "anti-aging" or other promises of youth by itself on the label or labeling of food products is unlikely to raise any red flags with the FDA. However, the issue becomes more complex when claims about specific conditions associated with aging are used. FDA has explained that mild conditions commonly associated with particular stages of life or normal physiological processes will not be considered diseases. The key for FDA (and labeling) is that the claims must relate to conditions that are a normal result of aging and not to disease-related conditions that are associated with aging. For example, FDA has stated that "mild memory loss associated with aging" will not be considered a disease, but FDA has objected to claims that reference Alzheimer's disease or dementia. Similarly, FDA has permitted claims concerning presbyopia (the inability to change focus from near to far and vice versa) associated with aging, but the agency objects to claims relating to glaucoma or cataracts. Other examples of conditions about which structure/function claims may be made include wrinkles, other signs of aging on the skin (e.g., liver spots, spider veins), and hair loss associated with aging. The following conditions are considered diseases and discussion of them should be avoided: osteoporosis and arteriosclerotic diseases of coronary, cerebral, or peripheral blood vessels.

FTC

FTC, the agency responsible for advertising, is concerned whether a company has competent and reliable scientific evidence to back up any claims it makes. For example, last year, FTC targeted companies that claimed that their pills and sprays would increase consumers' human growth hormone (hGH) levels and provide anti-aging benefits, including reduced weight, fat, blood pressure, cholesterol, or wrinkles and increased muscle mass, cognition, memory, libido, or skin quality. FTC objected to the claims because it believed that there was no scientific evidence in support of the claims.

Claims of specific results also present a potential problem with the FTC because they are often difficult to substantiate. For example, in order to substantiate a claim such as "take five years off the way you look," a company would need competent and reliable scientific evidence that most consumers will look five years younger after taking the product. That evidence must be in the form of well-designed, double blind, placebo controlled clinical trials on the products themselves. Unfortunately, such evidence is very expensive and thus rarely exists.

In general, it is unlikely that FDA and FTC will attack anti-aging claims in and of themselves. However, it is helpful to understand that the regulating agencies view such claims with skepticism and FDA has defined certain limitations on the use of the claims, as stated above in the FDA section.

Health Claim Updates

Canola Oil and Reduced Risk of Coronary Heart Disease Petition Filed

One new health claim petition was filed by the U.S. Canola Association seeking authorization to make claims concerning unsaturated fatty acids from canola oil and reduced risk of coronary heart disease. FDA accepted the petition after its initial review on March 2, 2006.

FDA Denies Whey Protein in Infant Formula and Reduced Risk of Food Allergies Claim

On May 11, 2006, FDA issued its decision on the partially hydrolyzed 100% whey protein in infant formula and a reduced risk of food allergy in infants health claim petition. The petition filed by Nestle USA had requested authorization to make the following qualified health claim for infant formula.

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research in healthy infants with family history of allergy shows that feeding a 100% Whey Protein Partially Hydrolyzed formula may reduce the risk of common food allergy symptoms, particularly allergic skin rash, when used instead of whole-protein cow's milk formula from the initiation of formula feeding. While this formula may reduce the risk, it is not intended to treat existing allergy symptoms. If you suspect your baby is allergic to milk, use only under a doctor's supervision.

Based on FDA's consideration of the scientific evidence, FDA concluded that there was no credible evidence to support the proposed qualified health claim.

http://www.cfsan.fda.gov/~dms/qhcwhey.html

FDA Denies Green Tea and Reduced Risk of Cardiovascular Disease Claim

On May 9, 2006, FDA issued its decision on the green tea and cardiovascular disease health claim petition filed by Ito En, Ltd. The petition sought authorization to make claims characterizing the relationship between the consumption of green tea and a reduction of a number of risk factors associated with cardiovascular disease. The proposed model health claim was as follows:

> Daily consumption of at least 5 fluid ounces (150mL) of green tea as a source of catechins may reduce a number of risk factors associated with cardiovascular disease. FDA has determined that the evidence is supportive, but not conclusive for this claim. (Green tea provides 125 mg catechins per serving when brewed from tea and 125 mg catechins as a pre-prepared beverage).

Based upon FDA's review of the scientific evidence, the agency concluded that there was no credible evidence to support the qualified health claim. This denial by FDA follows an earlier letter of enforcement discretion issued in response to a health claim petition regarding green tea and a reduced risk of cancer, as discussed in the 8th issue of the *Washington Food Report*.

http://www.cfsan.fda.gov/~dms/qhcgtea2.html

Qualified Health Claim Letters Offer Preview of Final Guidance on Substantiation

At a Food and Drug Law Institute conference, Dr. Barbara Schneeman stated that FDA's letters of enforcement discretion regarding qualified health claims provide the industry a rough outline of the agency's upcoming final guidance on health claim substantiation. Dr. Schneeman, who is the Director of the Office of Nutritional Products at FDA's Center for Food Safety and Applied Nutrition, discussed FDA's perspective on evidence submitted in support of health claims at the conference. Factors that the agency has been targeting include: poor controlling for confounding factors, use of NIH-validated biomarkers, studies in diseased populations, and submission of human studies.

February 27, 2006 edition of *The Tan Sheet*

FDA Issues Guidance on Implementation of "Qualified Health Claims"

FDA released final guidance on Implementation of "Qualified Health Claims" in the form of a question and answer document. The guidance clarifies the differences between health claims based on significant scientific agreement ("SSA") and qualified health claims. Although both types of health claims characterize a relationship between a substance (i.e., specific food component or a specific food) and a disease or health-related condition, and are supported by scientific evidence, the quantity of scientific evidence required to make the type of claim differs. The scientific evidence supporting a qualified health claim does not meet the SSA standard and therefore must be accompanied by a disclaimer or other language. In addition, the guidance also outlines the procedures for submitting and a timeline for review of a qualified health claim petition.

http://www.cfsan.fda.gov/~dms/qhcqagui.html

FDA Grants Excellent Source Claim for Foods Containing Both EPA and DHA

Ocean Nutrition Canada Limited was granted an excellent source nutrient content claim for foods containing both Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA) by the FDA. Previously, only DHA had been approved for an excellent source claim. This ruling will allow companies to include certain claims on their packaging such as "Excellent Source of Omega-3 EPA and DHA" or "High in Omega-3 EPA and DHA" followed by a statement that the product "Contains ___ mg of EPA and DHA per serving, which is ___ % of the 160 mg daily value for a combination of EPA and DHA," if the food products qualify. To qualify to make these claims, the products must contain a combined total of at least 32 mg of EPA and DHA per serving. 32 mg of EPA and DHA represents 20% of the daily value levels for EPA and DHA of the 160 mg per day.

http://www.npicenter.com/anm/templates/newsATemp.aspx?articleid=15489&zoneid=2

Regulatory Updates

U.S. Government Announces Model Food Emergency Response Plan

The FDA, the National Association of State Departments of Agriculture, USDA's Food Safety and Inspection Service and the Department of Homeland Security collaborated in creating a model Food Emergency Response Plan template. The template was developed after consultations with other federal agencies and state agencies and representatives. According to the FDA, the purpose of the response plan is "to enhance the protection of the nation's agricultural industry and food security through prevention, detection, response and recovery."

The template focuses on the following food-related emergencies - unintentional or deliberate contamination, threatened or actual, of food that impacts or may impact human health. States will be able to use the template to develop a plan that meets its particular circumstances but which will be similar in structure, scope and response of its operations to other states' operations.

The template contemplates a response plan including the following elements:

- Concept of Operations – Establishes a framework for actions that will take place during an incident;
- Activation Levels – Establishes activation levels that provide decision makers with definitions of various degrees of emergency;
- Principal Parties – Identification of all agencies, organizations and individuals needed to carry out a response; and
- Roles and Responsibilities – Identification of the roles and responsibilities for each state, federal, tribal, and local agencies and private sector.

http://www.fda.gov/bbs/topics/NEWS/2006/NEW01327.html

FDA Issues Guidance on Labeling Lecithin Derived from Soy

In April 2006, the FDA issued guidance on the food allergen labeling of lecithin derived from soy used as a releasing agent in food. Under the Food Allergen Labeling and Consumer Protection Act of 2004 ("FALCPA") (see 2006 U.S. Food Guide), sources of major food allergens must be labeled. Soybeans are a

major food allergen. Lecithin is a food ingredient that is derived from soy and other plant sources that has been affirmed as GRAS. Under FALCPA, lecithin from soy must be declared regardless of its technical or function effect in the finished food or use as an incidental additive. Food manufacturers use lecithin as an emulsifier, a stabilizer, a dispersing aid or an incidental additive as a release agent for baked goods.

FDA stated in the guidance that it will exercise enforcement discretion for foods with lecithin from soy that do not meet FALCPA's requirements if all of the following factors are present:

1. The food was labeled on or after January 1, 2006.
2. The lecithin derived from soy used as a component of a release agent satisfies each of the specifications for lecithin in the Food Chemicals Codex, 5th Edition.
3. The lecithin derived from soy is used solely as a component of a release agent as described in the guidance.
4. The release agent in which lecithin derived from soy is a component is used at the lowest level possible consistent with current good manufacturing practice.

FDA will reconsider its enforcement discretion in October 2007.

http://www.cfsan.fda.gov/~dms/soyguid.html

National Uniformity for Food Act Sparks Controversy

The National Uniformity for Food Act of 2005 (H.R. 4167) passed the House of Representatives in March 2006 and is now under consideration in the Senate. The Act would establish a federal standard for all food safety requirements and warning labels regulated by the FDA, thereby preempting any state regulations. Opponents to the bill argue that over 200 state food safety regulations would be preempted while supporters of the bill state that only 11 state rules would be affected. One of those 11 state laws/rules would be California's Proposition 65 which was summarized in the 2006 U.S. Food Guide.

http://www.foodnavigator-usa.com/news/printNewsBis.asp?id=67273
http://www.foodnavigator-usa.com/news/printNewsBis.asp?id=67231

Developments Concerning Benzene in Soft Drinks

Class action lawsuits have been filed against soft drink firms in five states alleging that the firms' products may contain cancer-causing benzene and therefore are not safe consumer products. There is no established safety limit for benzene in soft drinks, but the EPA has set a safety limit for bottled water of five parts per billion. The lawsuits charge that the soft drink firms manufacture products containing benzene above the EPA safety limit for bottled water, such that the products contain unsafe levels of benzene. A suspected source of the benzene is sodium or potassium benzoate and ascorbic acid. The two chemicals have the potential to react and create benzene in certain environments, like heat.

In an unusual flip of perspective, the soft drink industry has sought FDA's review of the product. The FDA, in response to reports of benzene in a variety of beverages, has initiated a survey of benzene levels in soft drinks. FDA's survey indicates that the vast majority of beverages contain either no detectable benzene or are well below the five parts per billion water standard. The FDA noted that it is checking with companies to ensure that processing conditions are established that will ensure that benzene formation is avoided or

minimized. In a statement, the agency provided that it believes that the results of the recent survey indicate that the levels of benzene found in soft drinks do not pose a safety concern.

In a related development, a new method for testing benzene content may soon be available. Under existing standards, the FDA tests for benzene in soft drinks by heating up the beverage—a process likely to promote additional benzene formation and skew results. The FDA is now investigating the work of James Neal-Kababick, an independent researcher who has developed a new process for benzene testing that operates faster and at lower temperatures. The FDA has been aware of the potential for benzene formation in any beverage containing both sodium benzoate and ascorbic acid (vitamin C) since 1990, but has not updated its testing methods in that fifteen year period.

http://www.cfsan.fda.gov/~dms/benzltr.html
http://www.beveragedaily.com/news/ng.asp?id=67096-fda-soft-drinks-benzene
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01355.html
http://www.foodnavigator-usa.com/nes/printNewsBis.asp?id=67151

Citizen Petition Filed to Revoke FDA's Approval of Splenda

Consumer advocate group, Citizens for Health, has filed a citizen's petition asking the FDA to withdraw Splenda, a zero-calorie sweetener, from the U.S. market until additional research can confirm its safety. The petition argues that the "there are potential public health concerns regarding sucralose that were dismissed by the FDA" when approved and that no human clinical studies have been conducted on the product. Splenda's manufacturer, Tate & Lyle rebut that argument stating that there is "no evidence that it [Splenda] causes any side effects whatsoever." McNeil Nutritionals, distributor of Splenda in the U.S., further notes that the safety of sucralose is well documented in more than 100 scientific studies conducted over a 20 year period. Tate & Lyle consider the filing of the petition by Citizens for Health as "another tactic in a long chain of orchestrated events led by organizations representing bodies with clear commercial interests."

http://www.foodnavigator-usa.com/news/ng.asp?id=66889-tate-lyle-mcneil-nutritionals-splenda-sucralose

FDA Increases Standards for Whole Grain Labeling

New FDA labeling guidelines will impose a consistent definition for "whole grain," a change designed to reduce consumer confusion about the best food sources for whole grains. Prior to these new guidelines, many food products had been labeled "good" or "excellent" sources of whole grains with little uniformity to the application of those terms; still other products were labeled "multigrain," although that designation did not necessarily speak to whole grain content.

The new FDA definition of "whole grain" requires a product to contain grains in their entirety—the starchy endosperm, the germ, and the bran, in roughly the same proportions as found in the intact grain. Eligible grains include barley, buckwheat, bulgur, corn (including popcorn), millet, rice, rye, oats (including rolled), sorghum, wheat and wild rice.

http://www.cfsan.fda.gov/'dms/flgragui.html

New Bill Proposes Overhaul of School Nutrition Standards

The Child Nutrition and School Lunch Protection Act of 2006, introduced in both the House of Representatives and the Senate, calls upon the USDA to update its nutritional standards for foods sold on school campuses. Under existing law, the USDA may set standards for foods sold in school lunchrooms, but is prohibited from regulating food sold elsewhere on school grounds. The new legislation proposes to extend regulatory authority to the entire campus and to revise the definition of "foods of minimal nutritional value," last updated in 1979. The specific details of any regulation would still be determined by the USDA.

The Child Nutrition and School Lunch Protection Act is sponsored by Senator Tom Harkin, Senator Lisa Murkowski, Senator Lincoln Chafee, and Senator Arlen Specter in the Senate. In the House of Representatives, the bill is sponsored by Representative Lynn Woolsey, Representative Christopher Shays, and Representative Nancy Johnson.

http://www.foodnavigator-usa.com/news/printNewsBis.asp?id=66943

California Withdraws Acrylamide Warning Rules

Facing "voluminous comments," the State of California's Office of Environmental Health Hazard Assessment (OEHHA) has withdrawn a proposed rule that would have required manufacturers to place acrylamide warning labels on food products. Acrylamide is a carcinogen created when starchy foods are cooked at high temperatures; under California law, manufacturers must warn consumers about the existence of cancer-causing compounds in their products. While there has been increased public pressure to require labels on products that might contain acrylamide, manufacturers argue that labeling would unnecessarily frighten consumers over trace amounts of a dangerous substance. OEHHA has plans to submit a revised labeling rule by summer 2006.

http://www.foodnavigator-usa.com/nes/printNewsBis.asp?id=66819

Revised Labeling Required for Poultry Products

As of March 2006, the Food Safety and Inspection Service now recommends more explicit labeling of uncooked poultry products. The new labels must state: "Uncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer." The new requirement is a response to recent consumer confusion and a rise in cases of sickness from *Salmonella enteritidis*. Last March, Serenade Foods voluntarily recalled 75,800 pounds of frozen stuffed chicken when it became apparent that consumers might believe the raw chicken entrees were pre-cooked.

http://www.foodnavigator-usa.com/nes/printNewsBis.asp?id=67043

USDA Publishes Organic Programs Rule

In compliance with recent amendments to the Organic Foods Production Act of 1990, the USDA published the final version of its National Organic Program regulations in the June 7, 2006 edition of the *Federal Register*. The final rule returns the use of non-organic substances in products labeled as "organic" to its status prior to the federal court ruling in *Harvey v. Johanns*. The rule also eliminates the "80/20" feed provision, which allowed dairy farms to use 20% non-organic feed during the first nine months of transition

from conventional to organic production. The USDA has indicated that it will engage in further rulemaking on this issue.

http://www.ams.usda.gov/nop/indexIE.htm

Consumer Survey Shows Popular Support for "Fat Tax"

According to a survey conducted by eDiets.com, 75% of participants would support a tax designed to discourage consumers from purchasing foods that are high in fat and low in nutrition. 38% of those surveyed said that a "fat tax" would not affect their purchasing decisions. 27% said that fast food is the "worst offending" form of junk food. While several U.S. cities already have a tax on certain prepared foods, the implementation of tax on fatty foods remains a largely controversial policy discussion.

http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=DIET&script=410&layout=6&item_id=840671

Industry Updates

Product Innovations

Frito-Lay Reduces Saturated Fats in Potato Chips

By switching to NuSun sunflower oil, Frito-Lay will decrease the saturated fats in its potato chips by more than 50% while increasing the healthier mono- and polyunsaturated fats. The potato chips already have zero grams of trans fats. Scientific research has shown that mono- and polyunsaturated fats have heart healthy benefits including lowering total and LDL cholesterol levels, and NuSun brand sunflower oil has higher levels of monounsaturated fat than regular sunflower oil.

Frito-Lay will market the switch in a summer promotion and full advertising campaign that will kick-off this spring.

http://www.foodnavigator-usa.com/news/ng.asp?n=67527&m=2FNU510&c=unpajoodmbwhash

7-Up Reformulated Using Only Natural Ingredients

Cadbury Schweppes has reformulated its 7-Up soda to use only five ingredients that are 100% natural. The five natural ingredients are filtered carbonated water, high fructose corn syrup, natural citric acid, natural flavors and natural potassium citrate. The reformulation may allow Cadbury to take advantage of the 15% growth in the natural soda market between 2004 and 2005. The U.S. carbonated drinks market, as a whole, has been stagnant, offering few growth opportunities according to analysts.

The Center for Science in the Public Interest ("CSPI") intends to file a lawsuit alleging that Cadbury Schweppes' all natural claim is misleading as the 7-Up soda contains high fructose corn syrup. CSPI will also seek restitution, corrective advertising and attorney's fees. The underlying issue in CSPI's suit is the current FDA policy on "natural" claims. Current FDA policy provides that a food can be considered to be natural if "nothing artificial or synthetic" has been added to it that would not normally be expected to be in that food product.

http://www.beveragedaily.com/news/printNewsBis.asp?id=67267
http://www.foodingredientsfirst.com/newsmaker_article.asp?idNewsMaker=10975&fSite=AO545&next=pr
http://www.beveragedaily.com/news/ng.asp?id=67688

Coors Light Unveils Stay Cold Glassware and Cold Wrap Bottles

Coors Brewing Company is debuting two new ways to keep Coors Light colder, longer which ties into its marketing slogan of "Taste the Cold." The first way is Coors Light Stay Cold Glassware, a dual-pane glass with a layer of air between the two panes of glass. The layer of air reduces the amount of heat transfer from a drinker's hand to the beverage. A cold beer poured into a Coors Light Stay Cold Glass is promoted as staying at the same cold temperature after 20 minutes. The second way is a Cold Wrap Bottle that has a 360 degree label made with Outlast technology. Outlast technology is supposed to reflect the heat from the hand, keeping the bottle and the beer inside colder, longer.

http://www.foodingredientsfirst.com/newsmaker_article.asp?idNewsMaker=10848&fSite=AO545&next=2

Jelly Belly Candy Co. to Offer Sports Beans

Jelly Belly Candy Co. has formulated Sports Beans as a jellybean carbohydrate supplement that will compete in the $3.2 billion market for energy drinks and bars. Sports Beans are available in lemon-lime, orange, fruit punch and berry blue. Each pack of 14 beans contains 25 grams of carbohydrates, 120 milligrams of electrolytes, extra vitamin C and E at 100 calories. According to Jelly Belly's website, the recommended dosage is one packet 30 minutes before exercising with a glass of water with the next dose 45 minutes later.

Research has shown that low blood glucose levels is a factor that contributes to fatigue during prolonged exercise. Sports Beans are being promoted as maintaining blood glucose levels during exercise. Jelly Belly is sponsoring a study by the University of California, Davis comparing the effectiveness of Sports Beans, energy gels and energy drinks against water to see which product does a better job of enhancing performance and warding off fatigue after prolonged exercise.

http://www.medicalnewstoday.com/medicalnews.php?newsid=41544&nfid=rssfeeds
http://www.nubella.com/content/view/1829/48/

Coca-Cola to Launch Godiva Belgian Blends

Coca-Cola Co. and Godiva Chocolatier are marketing a new line of indulgent, chocolate-infused coffee drinks. The new Godiva Belgian Blends brand will have three initial offerings – Dark Chocolate Mocha, Milk Chocolate Mocha, and French Vanilla Latte. The coffee drink will be sold in 9.5 fluid ounce glass bottles, in singles and in four packs, at a variety of outlets. The U.S. launch is scheduled for July 31, 2006.

http://www2.coca-cola.com/presscenter/newproducts_belgian_blends.html

Solex Imports Award-Winning Senorio de Montelarreina Cheese

Spain's Senorio de Montelarreina cheese was recently chosen as the best hard sheep milk cheese in a prestigious international competition. It beat two American brands from Wisconsin to earn the Gold Medal. Solex Partners Importers will distribute the Senorio cheese in the U.S.

http://www.hispanicbusiness.com/news/newsbyid.asp?id=33279

Bravo! Foods to Market General Mills' Cereal Flavored Milk

Pursuant to a five year licensing agreement, Bravo! Foods International Corp will produce and sell a line of vitamin-fortified milk with flavors based on General Mills Inc.'s cereals. Initially, Bravo! will market Trix, Cocoa Puffs and Wheaties flavored milk with the possibility of offering Lucky Charms, Count Chocula, Booberry and Frankenberry flavors later. In addition, Bravo! has the right to use the characters associated with each cereal. This agreement builds upon the current line of Bravo! vitamin-fortified milks that includes Starburst, Milky Way, 3 Musketeers and Moon Pie flavors. The Trix, Cocoa Puffs and Wheaties flavored vitamin-fortified milk will be launched in time for the fall school season.

http://www.bevnet.com/news/2006/04-20-2006-Bravo_gm.asp
http://twincities.bizjournals.com/twincities/stories/2006/04/17/daily47.html?t=printable

Mushrooms Exposed to UV Contain Large Amount of Vitamin D

A pilot study conceived by the FDA and funded by the Mushroom Council has shown that exposing just-picked edible mushrooms to ultraviolet light for five minutes drastically increases the vitamin D content of the mushrooms. The work, which is ongoing, has shown that a single serving of white button mushrooms contains 869% of the daily value of vitamin D once exposed to UV light after being harvested. Exposing growing or just harvested mushrooms to UV light is considered to be easy and cheap, if doing so would produce that quantity of vitamin D. Vitamin D is increasingly viewed as a factor in reducing the risk of osteoporosis, cardiovascular disease and tooth loss, and in reducing mortality associated with colon, breast, prostate and other cancers. If further research supports the pilot study findings, it could provide consumers with a new reason to eat mushrooms.

http://cbs4boston.com/food/local_story_108163944.html

BioCore – Comprehensive Digestive Enzymes

The National Enzyme Company formulated the BioCore Optimum supplement as an aid to ensure proper digestion of food. It contains fungal proteases that are active in different pH ranges in order to make sure protein digestion occurs in the stomach and small intestine. It also contains various carbohydrates to breakdown starch and lipases from various sources to break-down fats. BioCore also offers a supplement, BioCore Dairy, that is designed to bring relief to dairy intolerance. Dairy intolerance typically has two aspects – lactose intolerance and milk protein intolerance. BioCore Dairy is a blend of lactase and proteases that ameliorates symptoms of lactose intolerance and digests the milk protein, b-lactoglobulin, responsible for milk protein intolerance. BioCore Dairy Ultra includes the BioCore Dairy but also targets milk fat digestion.
http://www.nationalenzyme.com/biocore/
http://www.npicenter.com/anm/templates/newsATemp.aspx?articleid=15364&zoneid=22

Technology Updates

Ecolab Markets Antimicrobial Water Additive

Ecolab's Tsunami 100 is an antimicrobial water additive that is marketed as reducing pathogens in the water used to clean fruit and vegetables. The product is designed for use on vegetables and fruits, whole and cut, with no rinse required. It is the first product of its kind to register with the U.S. Environmental Protection Agency. According to Ecolab, Tsunami 100 works against E. Coli 0157:H7, Listeria monocytogenes and Salmonella enterica when added to processing water. It can be used in multi-stage flumes, chill tanks, coolers and washing in fresh cut, post harvest and further processing facilities. Because of the product's low reactivity with organics and soils in process wash waters, Ecolab promotes the product for its ease of maintaining a consistent dosage for microbial control.

Tsunami 100 is a timely additive as recent reports indicate that produce-related outbreaks of food poisoning tend to be larger than poultry-related outbreaks and sicken more people. Fresh produce triggered 554 outbreaks, causing illness in 28,315 people. In response to these outbreaks, FDA recently issued draft guidance on minimizing microbial food safety hazards of fresh cut produce, which is available at

http://www.cfsan.fda.gov/~dms/prodgui2.html.

http://www.foodnavigator-usa.com/news/printNewsBis.asp?id=67509

Patent Filed on Microwaveable Metal Foil

Qinetiq has filed a patent with the U.S. Patent and Trademark Office covering a thin polyester wrapping covered with tiny squares of a metal (like aluminum) that could be safely used in a microwave. The wrapping supposedly allows for heating in a microwave while still providing enough insulation for the product in its frozen or chilled state.

The patent claims that the amount of space between the squares of metal would be based on the wavelength of the microwave rays. In theory, the foil can be configured to optimize the heating conditions for different food stuffs by providing differing levels of microwave transparency or infrared reflectivity. Additional advantages to the foil are claimed to include: (a) acting as a barrier to chemical migration and permeation of oxygen into the food; and (b) significant reflectivity in the visible and ultraviolet radiation.

http://www.foodproductiondaily-usa.com/news/ng.asp?n=67245-foil-microwave-frozen

Moobella Unveils From Scratch Ice Cream Vending Machine

An ice cream vending machine, the Moobella Ice Cream System, is being touted as making from scratch and delivering ice cream in about 45 seconds. A consumer selects one of 95 combinations of flavors that the machine then instantaneously aerates, flavors, mixes and flash-freezes the ingredients to produce that ice cream. The machine offers both a premium ice cream using natural ingredients and a light ice cream with half the fat and 25% less calories. The company plans to market the machine to colleges, hospitals, cafeterias and other foodservice operators.
http://www.foodnavigator-usa.com/news/ng.asp?id=67419

Crown Food Begins Marketing Bowl-Shaped Cans in North America

Crown Food Europe is marketing its single-serving polymer coated steel bowl with a peelable lid in North America and Europe. The bowl-shaped cans cater to the ready-to-eat convenience products with its bowl-shaping and easy to open lids. The bowl-shaped cans allow a consumer to eat directly from the can while the can's metal composition helps maintain the food's flavor and sterility. The can is available in aluminum, steel and polymer-coated exteriors in a variety of volumes and finishes. Crown Food is marketing the can for use with tuna and meat salads, pates and spreads, puddings, and fruit and cream desserts.

http://www.packwire.com/news/printNewsBis.asp?id=67752

Cereal with Scented Packaging Coming Soon to Market

An unnamed cereal brand is set to launch with scented food packaging according to ScentSensational Technologies. ScentSensational Technologies claims to have pioneered the concept of incorporating food grade scents into plastic resulting in aromatic food packaging. The encapsulated aroma release allows manufacturers to give their product's packaging a desired scent increasing that product's appeal to consumers. The encapsulated aroma release can be used to cover the momentary off-smell experienced when opening a package or to lure consumers to the package (for example, bread bags incorporating the scent of fresh baked bread).

According to ScentSensational Technologies, no additional regulatory approvals are required prior to incorporation of the scents into the packaging materials because all ingredients used are approved for use in foods. In order to incorporate the scents into the plastic, changes are made to the concentrations of how and when the ingredients are used and not to the ingredients' molecular structure. The company notes that the use of the technology is "not at all expensive" and can be used for cereal, baked goods, yogurt cups, ready-to-eat soup bowls and beverage bottles.

http://www.packwire.com/news/printNewsBis.asp?id=68120

Treatt plc Introduces Blueberry Extract

Treatt plc's Blueberry Treattarome 9840 is derived from the American blueberry and is described as delivering a "well-rounded, authentic and ripe blueberry flavor with a floral topnote and a creamy, fruity finish." It can be used as either a sole flavoring or as an enhancer to existing recipes for dairy products, soft drinks, fruit juices, flavored waters and teas. Treatt produces Blueberry Treattarome 9840 by utilizing specialized low temperature distillation technology.

http://www.npicenter.com/anm/templates/newsATemp.aspx?articleid=15725&zoneid=59

Industry Trends

Expert Recommends Targeting Health, Ethnic Diversity and Convenience

At a recent trade show, keynote speaker Phil Lambert ("Lambert") stated that the key to building long-term relationships with consumers is to understand people and their different and changing needs. Lambert is considered to be a food trend expert. He noted that companies need to realize that one product for everyone in

the U.S. will no longer work. Products that cater to the different ethnic populations is a growing market. He also stated that consumers are increasingly focusing on health with less time to prepare, so companies that can educate a consumer about products' health benefits and brands can take advantage of this business opportunity area.

Virginia Dare, a New York-based flavor company, is following Lambert's advice and focusing on products that would appeal to the Latino market. The company conducted market research into the eating habits of the Latino populations and found that fruit flavors are consumed separately and that there are not a lot of citrus or berry flavors in Latino foods. Based on its research, the company is introducing three new mango flavors derived from different types of mangos and new fruit flavors for mojitos – guava, passion fruit, peach and strawberry. In addition, Virginia Dare is working on the development of pastries targeted to the Latino population with guava, pineapple and coconut flavors.

http://www.foodnavigator-usa.com/news/ng.asp?n=67475&m=2FNU510&c=unpajoodmbwhash
http://www.foodnavigator-usa.com/news/ng.asp?n=67466&m=2FNU510&c=unpajoodmbwhash

Current Trends in Lactose-Free Dairy Products

In recent months, the lactose-free dairy market has seen the expansion of the lactose-free milk market into the U.K. and Canada. In addition, the lactose-free specialty dairy market now includes the marketing of lactose-free doggie ice cream treats in the U.S. and lactose-free cow's milk formula for infants.

On the treatment side, Andrew J. Ritter of Los Angeles received a patent for his method of increasing lactose tolerance in individuals or mammals exhibiting lactose intolerant symptoms. According to the patent, the "method of increasing lactose tolerance in subjects exhibiting lactose intolerance symptoms implements a protocol where the subjects ingest a gradually increasing amount of lactose containing product over a six week period. At various points during the six-week period, the subject ingests the lactose containing product once a day and then twice a day."

If additional information on lactose-free dairy trends is sought, both the International Dairy Foods Association and the National Dairy Council have compiled industry trend information. To access that information, a company would need to join either organization.

http://www.preparedfoods.com/CDA/Archives/5adb0b9dd2bf9010VgnVCM100000f932a8c0____

Articles from *U.S. Fed News* (April 20,2006), *Progressive Grocer* (March 1, 2006), *Business Wire* (February 2, 2006), *Belleville Intelligencer* (February 14, 2006), and *PR Newswire US* (May 15, 2006)
http://www.idfa.org/econ/index.cfm
http://www.nationaldairycouncil.org/NationalDairyCouncil/Nutrition/Lactose/index.htm

Business Updates

Soft Drink Manufacturers Agree to Stop Sales of High Calorie Sodas in Schools

Coca-Cola, PepsiCo and Cadbury Schweppes have agreed with the American Heart Association to follow guidelines that limit the sales of beverages in elementary and middle schools to beverages with less than

100 calories. There are exceptions for milks and juices that have higher nutritional value. The guidelines will be effective starting in 2008 and covers about 87% of the school drink market.

The guidelines were reached after the ten largest school districts have removed carbonated beverages from vending machines. Some states, including California, Maine and Connecticut, have or are considering banning sales of sodas in schools. In addition, a bipartisan, bicameral group in Congress has introduced legislation aimed at improving the nutritional quality of foods sold in schools. The bill would require USDA to update its definition of "foods of minimal nutritional value." The USDA prohibits sales of "foods of minimal nutritional value" in the cafeteria alongside federally-reimbursed meals. But the current rules do not cover foods sold outside the cafeteria, like vending machines or snack bars.

http://www.drinks-business-review.com/article_news_print.asp?guid=331D7A05-E342-4002-BC84-ECB13457A50A

Willamette Valley Vineyards' Label Receives Approval for Antioxidant Content

Willamette Valley Vineyards has received approval from the Alcohol, Tax and Trade Bureau of the Department of Treasury for its Pinot noir wines to carry a label describing the antioxidant resveratrol and the resveratrol level in the wines. Based on recent research, resveratrol could block cancer cells from communicating with male hormones, thereby slowing the growth and reproduction of the cancer cells. However, the approved label does not make any health claims associated with resveratrol. The label only provides that "Pinot noir, a thin skinned winegrape, develops a natural defense against botrytis (mold) in our moist, cool climate – the antioxidant resveratrol."

Research by Dr. LeRoy Creasy at Cornell University has shown that the Pinot noir grape grown in moist, cool climates produces the most resveratrol. Dr. Creasy has stated that wine with greater than 10 micromolar of resveratrol is extraordinary and Willamette Valley Vineyard's 2004 Whole Cluster Pinot noir was tested as containing 71 micromolars.

http://www.willamettevalleyvineyards.com/pdf/pos/res_flyer.pdf
http://www.willamettevalleyvineyards.com/pdf/features/Cornell-creasy.pdf

NutraCea Doubles Capacity to Meet Increased Demand for Rice Bran

NutraCea has announced plans to double capacity at its Dillon, Montana plant to meet the increased demand for a stabilized rice bran product. Stabilized rice bran is a naturally rich source of vitamins, minerals and antioxidants that results from processing a by-product of rice. Demand for it is being fueled by large food manufacturers, like General Mills, who are increasingly using stabilized rice bran as a source for whole grain products. Last month, NutraCea secured a larger supply of raw rice, enabling it to supply its expanded processing plant. http://www.foodnavigator-usa.com/news/ng.asp?id=67022-nutracea-rice-bran-whole-grain

GRAS Updates

As of March 31, 2006, the FDA issued "no questions" letters for the substances below in 2006.

- L(+) Tartaric Acid - http://www.cfsan.fda.gov/~rdb/opa-g187.html
- Isomaltulose - http://www.cfsan.fda.gov/~rdb/opa-g184.html

- Phytosterols – http://www.cfsan.fda.gov/~rdb/opa-g181.html
- Allyl Isothiocyanate - http://www.cfsan.fda.gov/~rdb/opa-g180.html
- Polyclycerol Polyricinoleic Acid - http://www.cfsan.fda.gov/~rdb/opa-g179.html
- Sodium Iron EDTA - http://www.cfsan.fda.gov/~rdb/opa-g178.html
- Plant Sterols - http://www.cfsan.fda.gov/~rdb/opa-g177.html
- Plant Sterol Esters from Vegetable Oils or Sterols/Stanols from Tall Oil – http://www.cfsan.fda.gov/~rdb/opa-g176.html
- Saccharomyces cerevisiae strain ECMo01 with Enhanced Expression of Urea Amidolyase - http://www.cfsan.fda.gov/~rdb/opa-g175.html

Not U.S. articles

Tamper proof plastic – http://www.foodproductiondaily.com/news/printNewsBis.asp?id=67248

BASF – lycopene – study was done in Europe

FTC—Action on Food and Dietary Supplements

General Trends

Joint Report on Food Marketing and Childhood Obesity

In May 2006, the FTC and the Department of Health and Human Services issued a joint report recommending steps that industry can take to help combat the growing rates of childhood obesity in America. Since 1980, childhood obesity rates have tripled among adolescents and more than doubled in children under twelve. The agencies recommend that food companies:

- intensify their efforts to create new products and reformulate existing products to make them lower in calories, more nutritious, more appealing to children, and more convenient to prepare and eat;

- help consumers control portion sizes and calories through smaller portions, single-serving packages, and other packaging cues;

- explore labeling initiatives, including icons and seals, to identify lower-calorie, nutritious foods clearly and in a manner that does not mislead consumers;

- review and revise their marketing practices with the goal of improving the overall nutritional profile of the foods marketed to children, for example, by adopting minimum nutritional standards for the foods they market to children, or by otherwise shifting emphasis to lower-calorie, more nutritious products;

- generally explore ways to improve efforts to educate consumers about nutrition and fitness, with simple and effective messages; and

- review and revise their policies to improve the overall nutritional profile of the products they market and sell in schools.

The agencies will closely monitor industry progress in implementing the report, and one or both agencies will issue a follow up report within six months.

http://www.ftc.gov/opa/2006/05/childhoodobesity.htm

FTC Testifies on Dietary Supplements

On March 9, 2006, Lee Peeler, Deputy Director of the FTC's Bureau of Consumer Protection, testified before the House Committee on Government Reform. Mr. Peeler said: "Although many supplements offer the potential for real health benefits to consumers, unproven products and inaccurate information can pose a threat to the health and well-being of consumers and cause economic injury."

Mr. Peeler stated that the Commission would focus its enforcement priorities for the year on products and advertising claims with unproven benefits. Specifically, the FTC will concentrate on:

- Products promoted to treat or cure serious diseases;
- Products promoted for weight loss or muscle gain;
- Products that may present significant safety concerns to consumers; and
- Products that are deceptively marketed to or for children and adolescents.

The testimony included a digest of the fourteen complaints made in the past year against companies making allegedly unsubstantiated or false advertising claims for dietary supplements and other natural healthcare products. Over the same period, the Commission obtained orders against forty companies and forty-four individuals, prohibiting unlawful practices and requiring defendants to pay a total of $35.5 million in consumer redress, disgorgement, and civil penalties.

http://www.ftc.gov/opa/2006/03/dietarysupplements.htm

Disciplinary Actions

Sellers of Children's Weight Loss Product Settle FTC Charges

In April 2006, the FTC alleged that Dynamic Health of Florida, LLC, and Chhabra Group, LLC, the marketers of Pedia Loss, a child weight-loss supplement, and Fabulously Feminine, a female libido enhancement product, could not support claims that Pedia Loss causes weight loss in overweight or obese children or suppresses appetite, increases fat burning, and slows carbohydrate absorption. The FTC also alleged that the defendants could not support claims that Fabulously Feminine will increase a woman's libido, sexual desire, or sexual satisfaction. The settlement prohibits the defendants from making further unsubstantiated claims about the benefits of any dietary supplement or drug, and further bars the defendants from misrepresenting any test or study to substantiate future claims.

http://www.ftc.gov/opa/2006/04/dynamichealth.htm

"Garden of Life" Settles with FTC

Garden of Life, Inc., and its owner, Jordan S. Rubin, settled FTC charges that they made deceptive advertising claims about their supplements. The complaint targeted four dietary supplements: Primal Defense, RM-10, Living Multi, and FYI. The FTC recorded dozens of claims that the defendant's products cured ailments ranging from cancer to the common cold. The settlement requires any further claims by the defendants to be substantiated by competent and reliable scientific evidence. Garden of Life and Jordan Rubin will pay $225,000 in consumer redress as part of the settlement. If it is found they misrepresented their financial status to the FTC, they will be responsible for the full judgment of more than $47 million—the total gross sales of the four dietary supplements in question.

http://www.ftc.gov/opa/2006/03/gardenoflife.htm

FTC Charges Suppliers of Avlimil, Rogisen, and other Dietary Supplements

In February 2006, the FTC filed charges against Steve Warshak and his companies, which have marketed and sold more than a dozen dietary supplements in the United States—including Avlimil, Rogisen, and Enzyte. Defendants offered "free" samples through various advertisements, inviting consumers to contact them. The FTC alleged that after consumers provided credit or debit card information to pay the $4.50 shipping and handling fee for the samples, defendants used that information to bill the consumers for future shipments. According to the FTC complaint, defendants enrolled consumers in this "continuity program" and automatically billed them on a recurring basis without obtaining the consent of the consumers or disclosing the conditions of the plan. Consumers who attempted to cancel future shipments encountered busy telephone lines, broken Web sites, or were otherwise denied refunds.

The FTC also charged that defendants made false claims about their products. In their advertisement for treatment of female sexual dysfunction, defendants cited a clinical study that claimed Avlimil to be safe and effective. The FTC complaint demonstrated that Avlimil's ingredients differ substantially from the ingredients in the product actually tested in the clinical study referenced by the advertisement. Similarly, the FTC alleged that the defendants made unsubstantiated claims that another dietary supplement, Rogisen, improves night vision. The complaint did not include charges related to Enzyte, a supplement for "natural male enhancement."

http://www.ftc.gov/opa/2006/02/avlimil.htm

FTC Stops Ads for "Bio Trim" and Other Weight Loss Products

A November 2005 agreement with the FTC permanently prohibits California based Natural Products, LLC, All Natural 4 U, LLC, and their owner, Ana M. Solkamans, from making false and misleading claims about weight-loss products. The action stemmed from claims made in relation to a dietary supplement marketed in the United States as "Bio Trim," "Body-Trim/Bio-Trim," and "Body-Trim." The defendants' claims included that Bio Trim "guarantee[d] rapid weight loss" and that its users could "eat all [they] want and still lose weight." The order also prohibits the defendants from making further claims about weight-loss products or dietary supplements unless reliable scientific evidence substantiates the truth of the claim.

The action is considered a victory in last year's "Operation Big Fat Lie." As part of an initiative to crackdown on false weight-loss advertising, the FTC issued "Seven Red Flag Bogus Weight-Loss Claims" as a warning to both consumers and advertisers: "a claim is too good to be true if it says the product will 1) cause weight loss of two pounds or more a week for a month or more without dieting or exercise; 2) cause substantial weight loss no matter what or how much you eat; 3) cause permanent weight loss (even when you stop using the product); 4) block the absorption of fat or calories to enable you to lose substantial weight; 5) safely enable you

to lose more than three pounds per week for more than four weeks; 6) cause substantial weight loss for all users; or 7) cause substantial weight loss by wearing it on the body or rubbing it into the skin."

http://www.ftc.gov/opa/2005/11/biotrim.htm

http://www.ftc.gov/bcp/conline/pubs/buspubs/redflag.pdf

FTC Stops "Fountain of Youth" Oral Spray Advertising

In October 2005, at the request of the FTC, a federal district court issued a temporary restraining order against Pacific Herbal Sciences, Inc., its president, John A. Brackett, Jr., Natural Health Product, Inc., and New Star Marketing Group, Inc. and their president, Lei Lu, also known as Lei Li, also doing business under the name IE Marketing, Inc. The defendants are marketers of oral sprays who claimed that their products contained human growth hormone (HGH). The injunction prevents defendants from making allegedly false and deceptive claims and from sending illegal email spam. The FTC complaints alleged that the defendants had made false and unsubstantiated claims—notably, the defendants claimed that their products either contained HGH or increased the natural production of HGH, caused users to lose weight without diet or exercise, and were tested by credible scientific research.

In addition, the FTC charged that the defendants' Web sites were not encrypted or secure, as had been advertised. The FTC's complaint also contends that much of the email sent by the defendants to solicit consumers violated the CAN-SPAM Act and several subsequent federal regulations.

http://www.ftc.gov/opa/2005/10/pacherbal.htm

Defendants Banned from Marketing Seaweed-Based Patches in U.S.

In September 2005, after nearly two years of litigation, the Federal Trade Commission successfully reached a settlement with the manufacturers of Hydro-Gel Slim Patch and Slenderstrip, who are Kingstown Associates, Ltd., BVW Associates, Inc., Gary Bush, David Varley, and Laurence White.

The settlement against the United Kingdom-based defendants prohibits them from the future production, sale, or advertisement of dietary supplements and other weight-loss products in the United States. The defendants are also banned from making representations about the health benefits of any service or product unless such statements are substantiated by competent and reliable scientific evidence. The full judgment against the defendants was entered as $5.3 million—equal to the total U.S. sales of the two patches.

http://www.ftc.gov/opa/2005/09/hydrogel.htm

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