



MURPHY'S LAW

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Kirkpatrick & Lockhart LLP

FOOD & DRUG PRACTICE

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K&L Regulatory Update

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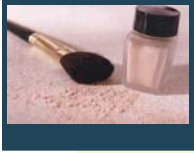
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GENERAL NEWS

- FDA defends its crackdown on Canadian drug imports
http://www.cbc.ca/stories/2003/04/03/Consumers/pharmacies_030403
- April K&L Alert on Proposed Changes to Fair Labor Standards Act
http://www.kl.com/files/tbl_s48News/PDFUpload307/8494/ela_2003-april-fairlabor.pdf
- Though cancer death rates for all Americans are falling, African Americans are still hardest hit
<http://www.msnbc.com/news/900225.asp>
- Interferon may help slow full diabetes onset
<http://www.chron.com/cs/CDA/ssistory.mpl/metropolitan/1869302>
- FDA has published a Notice of Intent to Withdraw Certain Proposed Rules and Other Proposed Actions published over five years ago
<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-9865.pdf>
- With HIPAA Comes...Confusion
<http://www.baltimoresun.com/news/health/bal-privacy23apr23,0,3466613.story?coll=bal%2Dhome%2Dheadlines>
- K&L Alert: California Legislators Introduce a Plethora of Proposed Amendments to the Unfair Competition Law
http://www.kl.com/files/tbl_s48News/PDFUpload307/8524/cla_0403.pdf

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COSMETICS

Regulatory Update

- FDA published its 2004 guidance agenda on April 4. Included are plans for a draft guidance requiring warning statements for cosmetic products that can't substantiate safety due to insufficient data and a Cosmetics Handbook for Industry guidance. Comments are requested on the agenda <http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-8262.pdf>
- The National Toxicology Program (“NTP”) has released a monograph evaluating di-n-butyl phthalate, one of the most common phthalates found in cosmetics. While the Cosmetic Ingredient Review Expert panel has recently found this and other phthalates safe as used in cosmetics, the NTP expressed “some concern” about that the chemical may have adverse effects on human development, especially with regard to reproductive development. http://cerhr.niehs.nih.gov/news/phthalates/DBP_Monograph_Final.pdf
- The Cosmetic, Toiletry and Fragrance Association (“CTFA”) has submitted comments to FDA on the agency’s Draft Guidance for Industry on Labeling Cosmetic Products Containing Topically Applied Alpha Hydroxy Acids as Ingredients <http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020403/8004d35c.pdf>
- Procter & Gamble also submitted comments on the AHA draft guidance <http://www.fda.gov/ohrms/dockets/dailys/03/Jan03/013103/8004ca71.pdf>

Enforcement Update

- Recall of Cosmeceutical Creations mascara because of bacteria http://www.fda.gov/oc/po/firmrecalls/cosmeceutical04_03.html

Safety and Effectiveness Update

- Aubrey Organics has introduced a new line, Natural Spa. It is the company’s first line made to comply with the standards of the USDA National Organic Program (“NOP”). Products in the line that are certified 95% to 100% organic will bear the USDA Organic seal. Products that are certified as being over 70% organic will be labeled ‘organic.’ The Natural Spa line is Aubrey’s first venture into the spa product category. For a look at the product line, follow the link below: <http://www.aubrey-organics.com/categories1.cfm>
- A study in the March 13 New England Journal of Medicine reported that sensitization to peanut protein could occur in children through application of peanut oil to inflamed skin. <http://content.nejm.org/cgi/content/abstract/348/11/977>
- The National Advertising Division (“NAD”) of the Better Business Bureau recently found, following an inquiry, that CCA Industries should remove references to cosmetic scar reduction benefits from its OTC Drug Facts box on its Sudden Change Scar Zone cream. NAD concluded that consumers could interpret the product’s labeling as meaning the FDA had approved it as a drug effective in diminishing scars. The product is OTC because it contains sunscreen ingredients, though its sun protection benefits are listed below scar diminishment claims in the Drug Facts box.

- NAD has also concluded that the small study submitted by Body Innovations to support claims for its Bust Booster Breast Enhancement product were not sufficient evidence to support specific claims for product performance. In the study, participants subjectively reported on size increase after application of the ointment. NAD recommended that Body Innovations discontinue product claims for dramatic and magnificent new proportions in size, weight and cup size visible in seconds after application.
- NAD also found that Voluptas International failed to substantiate performance and health-related claims with reliable and competent scientific evidence. The maker of Voluptas tablets and crème advertised its products as increasing breast tissue size through a pharmacological effect. Voluptas failed to provide evidence that its products had been clinically tested for safety and efficacy and agreed to modify or discontinue its advertising claims.
- Discus Dental bickered with NAD over claims for its Zoom! Chairside Tooth Whitening System. NAD found that there was enough evidence for to support a product parity claim against one competing product, but that Zoom!'s could not demonstrate parity with a challenger's product. NAD also pointed out that Zoom!'s claims implied superiority against all contenders, a burden of proof Discus Dental admitted it could not meet. Discus Dental disagreed that the company inadequately supported its parity claim against the challenger product, but said it would take NAD's recommendations into account in preparing future advertising claims.
- The EPA is releasing a preliminary risk assessment and seeking comment on perfluorooctanoic acid ("PFOA"). The substance is used in the manufacture of many products, including cosmetics, Teflon and stain resistant clothing. The EPA became very concerned about the compound upon reading a study by 3M showing PFOA may cause developmental toxicity, as well as having other negative health effects.

<http://www.epa.gov/fedrgstr/EPA-MEETINGS/2003/April/Day-16/m9418.htm>



DIETARY SUPPLEMENTS/FOOD

Regulatory Update

- FDA publishes Juice HACCP Small Entity Compliance Guide
<http://www.fda.gov/OHRMS/DOCKETS/98fr/03d-0093-gd10001.PDF>
- The American Heart Association is urging a ban on ephedra supplements
<http://www.cnn.com/2003/HEALTH/04/03/health.ephedra.reut/>
- The FDA is reviewing a Citizen Petition requesting the agency rescind the GRAS status of aluminum containing food additives. The Citizen Petition cites studies finding dietary aluminum linked with Alzheimer's disease
FDA letter: <http://www.fda.gov/ohrms/dockets/dailys/03/Jan03/012903/8004c792.pdf>
Citizen Petition: http://www.fda.gov/ohrms/dockets/dailys/02/Jan02/011102/02p-0013_cp00001_01.pdf
- Public Citizen's Sidney Wolfe, M.D. has published an article in Science magazine on the state of ephedra regulation.
<http://www.citizen.org/publications/release.cfm?ID=7241>
- California is considering water quality reporting rules for bottled water
<http://www.salon.com/mwt/wire/2003/04/09/water/index.html>
- The American Medical Association has submitted comments on FDA's Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/022403/02d-0515-c000002-01-vol1.pdf>

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- FDA denies a petition to restrict supplement claims
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021403/80050336.pdf>
- New dietary supplements 75-day premarket notices
 - Pure Research Products Naturally LLC:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021303/95s-0316-rpt0144-01-vol102.pdf>
 - Neptune Technologies and Bioresources:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021303/95s-0316-rpt0145-01-vol103.pdf>
 - Heartmind Nutrition:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021303/95s-0316-rpt0146-01-vol104.pdf>
 - Pharmax LLC:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021303/95s-0316-rpt0147-01-vol105.pdf>
 - Perrigo Company:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021303/95s-0316-rpt0148-01-vol106.pdf>
 - Triarco Industries:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021303/95s-0316-rpt0149-01-vol107.pdf>
 - Synorx, Inc.:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021303/95s-0316-rpt0150-01-vol108.pdf>
 - Biodynamics NV:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004db32.pdf>
 - Homegi Biotech International Corp.:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004e59e.pdf>
 - Trinity International, LLC:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004e59e.pdf>
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004dff5.pdf>
 - Premiere Towa, Inc.: <http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004e58b.pdf>
 - Yat Chau (USA) Inc.:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004db33.pdf>
 - Yat Chau (USA) Inc.:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004db34.pdf>
 - Yat Chau (USA) Inc.:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004db36.pdf>
 - Belova Inc.: <http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004db36.pdf>
 - Phytos, Inc.: <http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020703/8004e03d.pdf>
 - Clover Corp. Ltd.: <http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020403/8004daff.pdf>
 - FDA letter to stakeholders listing backlogged notices now placed on file in docket:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020303/8004cd78.pdf>
 - The Remedy Company:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020303/8004cd7a.pdf>
 - Lane-Labs USA: <http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020303/8004cd84.pdf>
 - American Research Institute of World Traditional Medicine:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020303/8004cda3.pdf>
 - Pure Research Products Naturally, LLC:
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020303/8004cda4.pdf>

— Chemi Nutraceuticals:

<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020303/8004cdce.pdf>

— Herbs Generation Int'l. Ltd.:

<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020303/8004cdb3.pdf>

- FDA responds to a letter from the Center for Science in the Public Interest urging that the amount of caffeine per serving should be declared on labels of foods containing caffeine
<http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/030703/97p-0329-let0007-vol4.pdf>

Enforcement Update

- A supplement maker is recalling its sexual stimulant herbal mix after FDA found it contained traces of Viagra
http://www.usatoday.com/news/health/2003-04-07-vinarol-recall_x.htm
- A Seattle law firm is launching a lawsuit against three of the U.S.'s largest grocery companies, alleging that it is unfair, against federal law and deceptive to sell salmon that has artificially been colored pink without informing shoppers. Wild salmon acquire their pink color from their diet, but farmed salmon are given feed with added pigment to produce the pink color.

Safety and Effectiveness Update

- Enhanced waters are booming in popularity but, one reporter asks, are they good for you?
<http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2003/04/02/FD152448.DTL>
- Eating fish linked to mercury levels in some women. Women of childbearing age advised to watch fish consumption
<http://www.4woman.gov/nwhic/News/2003/03apr2-1.htm>
Experts say fish may be eaten often, if one chooses the fish carefully
<http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2003/04/16/FD292999.DTL>
- Researchers are exploring Vitamin A and why it seems to boost the immune system in fighting certain diseases, though not others
<http://www.foodnavigator.com/news/news.asp?id=7360>
- Flax seed outperformed soy in recent studies of reduction of cholesterol and liver fat levels
<http://www.naturalproductsinsider.com/hotnews/34h413149.html>
- Calcium helps girls diet and keep weight off
<http://www.healthscout.com/printerFriendly.asp?ap=68&id=512583>
- Studies find our dietary urges for high fat foods are hard-wired
http://magazines.ivillage.com/goodhousekeeping/hb/news/article/0,,krt_2003_04_16_kniga_0537-0016-SCI-CRAVING~SE~ew~xml,00.html
- An article examining the body's need for water, and the effects of skimping on liquids
http://www.rockymountainnews.com/drmn/health_and_fitness/article/0,1299,DRMN_26_1887793,00.html
- Just when you thought tea couldn't get any better for you, it does
<http://news.bbc.co.uk/2/hi/health/2955491.stm>
- Lifestyle changes, including healthy diet, can cut the risk of high blood pressure
<http://www.post-gazette.com/healthscience/20030423heart0423p3.asp>

Business and Industry Update

- A new book advocates unifying U.S. food regulation under one agency
http://www.usatoday.com/news/health/2003-04-02-foodsafety-usat_x.htm

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- The late Dr. Atkins created a \$100 million dollar empire with his controversial diet advice
<http://www.business2.com/articles/mag/0,1640,47902,00.html>
- An Oregon court ordered Carolwood to pay damages for failing to pay royalties to the patent holders when selling MSM (methylsulfonylmethane)
<http://www.naturalproductsinsider.com/hotnews/34h816550.html>
- Starbucks to buy Seattle's Best North American operations
<http://www.lohasjournal.com/app/cda/nbpCDAArticlePrint.php?articleId=3906&categoryId=4>
- The U.S. sugar industry fights back on the WHO recommendation that sugar should constitute up to 10% of diet
<http://www.foodnavigator.com/news/news.asp?id=7485>

Legislative Update

- The passage of a bill sponsored by Senator Leahy (D-VT) has closed the special interest loophole in organic legislation that allowed meat and dairy products to be labeled organic, even when they were not
<http://www.naturalproductsinsider.com/hotnews/34h10155827.html>
- On the heels of closing the organic definition loophole for meat and poultry, Congress has passed an amendment to the National Organic Foods Production Act that allows wild fish to be labeled as organic. The Organic Trade Association (“OTA”) points out that “the term ‘organic’ on a food product really describes a complete system of production that begins on a farm,” and that “standards for organic agricultural production do not readily translate to a water-based system.” OTA further stated that the amendment disregards the basic concepts inherent in organic product labeling in that there is no way to ensure what wild aquatic animals are eating or to monitor the health of individual animals.



OTC DRUGS

Regulatory Update

- SinoFresh Research Labs has submitted a Citizen's Petition requesting inclusion of a nasal spray with 0.05% cetylpyridinium chloride in the tentative final monograph for Oral Antiseptic Drug Products
<http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/032503/81n-033a-cp00001-01-vol16-web.pdf>
- Bayer has petitioned FDA to amend the Final Rule for the Professional Labeling of Aspirin to include additional health claims
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021403/800511e0.pdf>
- Final Rule on Labeling for Oral and Rectal OTC Drug Products Containing Aspirin and Nonaspirin Salicylates: Reye's Syndrome Warning
<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-9382.pdf>
- FDA issues final monograph on 'Antidiarrheal Drug Products for OTC Human Use'
<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-9382.pdf>

Published also with its first proposed amendment:

<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-9381.pdf>

- FDA responds to a Citizen Petition requesting that FDA refrain from enforcement action after November 5, 2002 against any maker of OTC stimulant laxative drug products that contained casanthranol or cascara sagrada
<http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/031103/78n-036L-let0198-vol121.pdf>
FDA had the same response to a Citizen Petition submitted jointly by the American Herbal Products Association and the International Aloe Science Council
<http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/031103/78n-036L-let0199-vol121.pdf>
- Though Allegra and Zyrtec manufacturers are opposed to it, FDA wants to take the products OTC (see related stories on competition with Claritin below in Business & Industry Update)
http://www.usatoday.com/news/health/2003-04-22-fda-usat_x.htm
- As part of its “Drug Quality System for the 21st Century initiative,” FDA has asked for stakeholder input on the continuing relevance of pre-approval inspections (“PAI”). As a discussion point for a recent FDA-sponsored workshop, FDA asked if PAI had outlived its usefulness and should be eliminated. The agency is also asking for input on the most effective role of inspections
<http://www.fda.gov/cder/gmp/breakout-CMCreview.htm>

Enforcement Update

- NBTY’s poor recordkeeping of pseudoephedrine mail-order sales in the U.S. and abroad may cost the company millions in injunctive relief under the Controlled Substances Act
<http://www.naturalproductsinsider.com/hotnews/34h18141613.html>
- Bayer and Glaxosmithkline will pay \$344 million to resolve allegations of health care fraud against state programs
<http://www.newsalert.com/bin/story?StoryId=CpPZvqbWbtKvxmdqX&FQ=fda&Nav=na-search-&StoryTitle=fda>
- Maker of Skin Zinc Spray and Skin Zinc Cream receives warning letter for lack of NDA
http://www.fda.gov/foi/warning_letters/g3948d.htm

Business and Industry Update

- Changing Claritin to OTC means that health plans are no longer covering it
http://seattlepi.nwsourc.com/local/115809_callergy04.shtml
And many insurers are also making it harder to get the competing prescription medications
<http://www.cnn.com/2003/HEALTH/conditions/04/23/allergy.drugs.ap/index.html>
- How will Allegra fare against OTC Claritin?
http://www.forbes.com/home_europe/newswire/2003/04/07/rtr931593.html
- Michigan Supreme Court has ruled that pharmaceutical companies cannot be sued for product liability over an alleged design problem or design defect, if the product has been approved by FDA
[http://courtofappeals.mijud.net/documents/opinions/final/sct/20030326_s120645\(129\)_taylor7-10dec02.op.pdf](http://courtofappeals.mijud.net/documents/opinions/final/sct/20030326_s120645(129)_taylor7-10dec02.op.pdf)
- Despite the coverage of a crackdown on Canadian storefronts, some say its all talk and no action
<http://www.miami.com/mld/miamiherald/business/5685114.htm>



MEDICAL DEVICES

Regulatory Update

- FDA published a proposed rule on March 20 that would make silicone sheeting for the treatment of intact hyperproliferative skin nonprescription Class I exempt devices. Comments are due by June 18, 2003:
<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-6646.pdf>
- CDRH updates its “Device Advice” page on 510(k) review fees with relevant information for 2003
<http://www.fda.gov/cdrh/devadvice/314a.html>
- Advamed requested clarification from FDA about when a device manufacturer should sign a business associate agreement with a health care provider that would be covered by HIPAA
Advamed request: <http://www.advamed.org/publicdocs/ltr.%20richard%20campanelli.pdf>
FDA response: http://www.advamed.org/publicdocs/hhs_hipaa_response_2003.pdf
- FDA responded to a letter from Senator Feingold on a bill that would prohibit the use of mercury in dental fillings. The agency stated it has not taken a position on the bill
<http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/022003/80050b3b.pdf>
- FDA responds to a Citizen Petition requesting FDA take general action in regard to all pre-clearance inspections for broad categories of medical devices
<http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/030403/01p-0389-pdn0001-vol1.pdf>
- FDA publishes notice of modifications to the list of recognized standards for use in premarket reviews
<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-10417.pdf>

Enforcement Update

- Worldwide sales of Gynecare Intergel surgical gel have been suspended pending a probe into adverse event reports
<http://www.wounds1.com/news/mainstory.cfm/0>
- Pulmonetic Systems receives a warning letter for deficiencies in device manufacturing quality systems
http://www.fda.gov/foi/warning_letters/g3950d.htm
- Portable anesthesia device maker Cardinal Medical Specialties also received a warning letter on quality systems deficiencies
http://www.fda.gov/foi/warning_letters/g3947d.htm

Safety and Effectiveness Update

- Researchers are seeking a contact lens that can measure glucose levels in diabetics
<http://www.msnbc.com/news/901650.asp?0cv=HB10>

Business and Industry Update

- Canadian pharmacies, where the Today sponge has been on the market for a month, are swamped with requests from American consumers
http://www.usatoday.com/news/health/2003-04-07-sponge_x.htm

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INTERNATIONAL UPDATE

Europe

- In the March issue of Cosmetics & Toiletries magazine, Colipa's Secretary General Bertil Heerink spoke about the EU decision to ban animal testing for cosmetics in the 7th Amendment to the Cosmetics Directive. Heerink said that Colipa's major task will be 'to focus on appropriate implementation of the directive for legal requirements.' He forecast that the organization and its members will be called upon to share information and schedule and plan activities that convey an understanding of the technical, legal and economic business impact of the Amendment. More immediately, Colipa is planning to engage in a business impact assessment. Heerink saw the search for alternative testing methods as the biggest challenge for the cosmetics industry. He also called attention to the global nature of developing alternative testing methods. Heerink mentioned a new pilot project, set up by E.U. and U.S. regulators in cooperation, intended to promote international recognition and validation of alternative test methods.

The magazine issue can be ordered from http://www.thecosmeticsite.com/ct/ct_home.html#

- Denmark chocolate company Cocio has unveiled a controversial new product – chocolate milk spiked with vodka or cognac http://www.just-food.com/news_detail.asp?art=53899
- At the Copenhagen New Functional Foods and Ingredients conference, it was reported that patients being treated with cholesterol lowering statins experienced significant additional effects with Nutri Pharma's patented soy composition Abacor. For every 6% reduction in LDL cholesterol, the dosage of statin would need to be doubled. In the company's study, they found that, with Abacor, male participants achieved an additional 12% reduction of LDL cholesterol without increase to statin dosage. Additional study results on Abacor presented at the conference found that the soy product is more than twice as effective in lowering cholesterol than the best commercially available soy protein.

Asia/Pacific

- The Australian Therapeutic Goods Administration ("TGA") has suspended Pan Pharmaceuticals manufacturing license due to serious good manufacturing practice deficiencies, including manipulation of quality control data. TGA has identified over 200 products for immediate recall, including all nutritional products, and canceled the company's permission to export. <http://www.naturalproductsinsider.com/hotnews/34h28131123.html>
- Two U.S. entities have filed trademark infringement suits against two Korean domestic companies. Stout Hotels and Resorts Worldwide plans to open a hotel in Seoul later this year to be called the "W Seoul Walkerhill," but first they are suing the owner of the Korean company "W Bar" because the "W" is identical to their own mark. Stout seeks approximately US \$80,000 in compensation. Meanwhile, the Korean Harvard Language Institute is being sued by Harvard University, who claims that the Institute cannot use "Harvard" as its sign on the Internet. The university claims that the use of "Harvard" leads Institute customers to believe a special relationship exists between the two entities. The University registered its mark with KIPO in 1993.
- Korean company Ineworld has developed a chainless bicycle, called The Magic Bike. Without a chain, only constant peddling can keep the bicycle in motion. Ineworld projects that the cycle will therefore be attractive for aerobic exercise. The company has put the design under patent application in 10 countries worldwide.

- Japan's Kao Corporation is preparing to launch a green tea geared to accelerate fat loss. Healthya Green Tea will roll out on May 26 in Tokyo and surrounding areas. The beverage will be sold in 350 ml bottles and contains catechin, a tannin that assists the body's metabolism in burning fat at a faster rate than with regular green tea.

The Americas

- Canada's Minister of National Revenue has announced that, effective April 2004, Canada will implement a 24-hour notification rule for marine shipping destined for Canada and being loaded at a foreign port. The rule will be supplemented by complementary rules for land and air freight. <http://www.cra-adrc.gc.ca/newsroom/releases/2003/apr/cargo-e.html>
- Canada's Waste Diversion Ontario is seeking public comment on their Blue Box Program Plan. The plan will mandate that brand owners and first importers of packaging materials that are classified as 'blue box' waste (according to the color of the designated receptacle) will be responsible for sharing funding of the province's waste diversion program. Affected companies include makers of rigid plastic containers. Companies should have received notification of potential obligation in April and the first fee payments will be due on July 1, 2003. <http://www.ene.gov.on.ca/envision/land/wda/index.htm>



MEETINGS AND CONFERENCES

05/02/03 – 05/07/03	SupplySide East 2003 for Healthy Product Suppliers and Manufacturers	Meadowlands Exposition Center Secaucus, New Jersey U.S.A. More info: +1-480-990-1101 Ext. 1543 http://www.supplysideshow.com/east/
05/04/03 – 05/07/03	International Chain Salon Association Annual Conference	Loews Resort South Beach, Florida, U.S.A. More info: (866) 444-4272
05/05/03 – 05/09/03	CDER 101	Doubletree Hotel & Executive Meeting Center Rockville, Maryland U.S.A. More info: (301) 770-2920 Regulatory Affairs Professional Society Email: raps@raps.org http://www.raps.org/
05/06/03 – 05/09/03	Consumer Specialty Products Association Mid-Year Meeting	Downtown Marriott, Chicago Illinois More info: CSPA (202) 872-8110
05/08/03 – 05/09/03	AdvaMed: MDR and Vigilance Reporting	Washington D.C. For more information: http://www.advamed.org/mtli/
05/08/03 – 05/09/03	SCC Annual Scientific Seminar	JW Marriott, Washington D.C. More info: (212) 668-1500 Email: scc@scconline.org www.scconline.org
05/12/03	FDLI: How to Work with the FDA	Chicago, Illinois U.S.A. More info: (800) 956-6293; (202) 371-1420 E-mail: Comments@fdli.org

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05/13/03 – 05/14/03	Conducting Clinical Trials for Medical Devices	Harrington Hall Hotel London, England More info: +44(0) 1483 570099 Email: info@management-forum.co.uk http://www.management-forum.co.uk/meddevices.htm
05/13/03 – 05/14/03	FDLI: Introduction to Food Law and Regulation Workshop	Chicago, Illinois U.S.A. More info: (800) 956-6293; (202) 371-1420 E-mail: Comments@fdli.org
05/13/03 – 05/15/03	VitaFoods International 2003	Palexpo Centre Geneva, Switzerland More info: +44 (0) 20 7344 3854 Email: vitafoods@iirx.co.uk http://www.vitafoods.co.uk/
05/13/03 – 05/15/03	HBA South America	Sao Paulo Brazil More info: 55-11-3873-0081 ext. 111 Email: hba@vnu.com.br http://www.hbaexpo.com.br
05/15/03 – 05/18/03	Congress of Cosmetic Chemistry: Quality and Trends in Cosmetics	Hotel Paradisus Riviera, Cancun, Mexico More info: 52-5-688-29-11 E-mail: sqcm@terra.com.mx http://www.terra.com.mx
05/26/03 – 05/28/03	Beauty World Japan	Tokyo, Japan www.beautyworld.messefrankfurt.com
05/31/03 – 06/02/03	International Esthetics, Cosmetics, Spa Conference	Las Vegas Convention Center Las Vegas, Nevada, U.S.A. More info: (800) 624-3248 www.magda.com
06/02/03 – 06/04/03	Ingredients Expo 2003	Jacob Javitz Convention Center New York, New York U.S.A. More info: http://www.devicelink.com/cgi/inquiry/index.cgi?show=nu03 http://www.devicelink.com/expo/nu02/
06/03/03 – 06/05/03	Euroforum and Beauty-on-Line: The 7th Amendment to the European Cosmetics Directive	Paris, France More info: Anna Gallone Tel: +33 1 44 88 16 84 www.euroforum.fr
06/03/03 – 06/06/03	Expo Pack Mexico 2003	Expo Sante Fe, Ciudad de Mexico Mexico City, Mexico http://www.expopack.com.mx/index_ing.htm
06/05/03	Independent Cosmetic Manufacturers and Distributors Annual Meeting and Entrepreneur Awards	New York City, New York, U.S.A. More info: (800) 334-2623 Email: info@icmad.org http://www.icmad.org

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06/05/03 – 06/06/03	RA/QA	Radisson Hotel Alexandria, Virginia U.S.A. More info: (301) 770-2920 Regulatory Affairs Professional Society Email: raps@raps.org http://www.raps.org/
06/06/03 – 06/08/03	Cosmofarma	Bologna, Italy More info: (39) 02-796-420 Email: sogecos@cosmoprof.com
06/07/03 – 06/10/03	National Association of Chain Drug Stores: Marketplace Conference	San Diego, California Contact: NACDS Meetings Department (703) 549-3001 Email: meeting_info@nacds.org http://meetings.nacds.org/conferences/nacds_main.cfm?page_id=493
06/09/03 – 06/10/03	FDLI: Introduction to Drug Law and Regulation Workshop	Westin Grand Hotel Washington D.C. U.S.A. More info: (800) 956-6293; (202) 371-1420 E-mail: Comments@fdli.org
06/10/03 – 06/11/03	Luxe Pack New York	Metropolitan Pavilion New York, New York U.S.A. More info: KX Associates (212) 925-2507
06/10/03 – 06/11/03	AdvaMed: Advanced Complaint Handling	Washington, D.C. For more information: http://www.advamed.org/mtli/
06/12/03 – 06/13/03	Global Beauty Congress & Natural Personal Care Products Conference	Chicago, Illinois, USA More info: (212) 621-4978 Email: reg@chemweek.com http://www.cwacts.com
06/14/03 – 06/17/03	AAMI 2003 Annual Conference and Expo	Long Beach, California U.S.A. More info: (800) 332-2264 Association for the Advancement of Medical Instrumentation www.aami.org
06/17/03 – 06/18/03	Active Ingredients Conference	Le Palais de Congrès Paris, France More info: Step Exhibitions Ltd. (44) 1892-518877 Email: active@stepex.com www.stepex.com
06/18/03 – 06/20/03	Natural Products Expo Asia 2003	Hong Kong, China International Contacts for information: http://www.naturalproductsasia.com/naturalproductsasia/eng_contactus.html General Expo information site: http://www.naturalproductsasia.com/naturalproductsasia/index.html

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06/19/03 – 06/21/03	CIES World Food Business Summit	Atlanta, Georgia U.S.A. Contact: + 1 301 563 3383 Fax + 1 301 563 3386 Email: us.office@ciesnet.com www.ciesnet.com
06/26/03 – 06/27/03	AdvaMed: Setting Up an Effective Corrective and Preventive Action System	Chicago, Illinois, U.S.A. For more information: http://www.advamed.org/mtli/
06/30/03 – 07/02/03	NAFTS International Food Convention and Summer Show	Jacob Javitz Convention Center New York, NY U.S.A. Contact : (212) 482-6440 www.specialty-food.com
07/09/03 – 07/10/03	AdvaMed: QSR and 13485	Washington D.C., U.S.A. For more information: http://www.advamed.org/mtli/
07/21/03	Due Diligence	Doubletree Hotel & Executive Meeting Center Rockville, Maryland U.S.A. More info: (301) 770-2920 Regulatory Affairs Professional Society Email: raps@raps.org http://www.raps.org/
07/22/03 – 07/23/03	AdvaMed: Revelations From Former FDA Officials: What FDA Teaches its Investigators About Inspections and Evidence Development	Irvine, California, U.S.A. For more information: http://www.advamed.org/mtli/
07/28/03 – 07/30/03	Cosmoprof North America	Las Vegas, Nevada, U.S.A. More info: (39) 02-796-42 Email: sogecos@cosmoprof.com
08/06/03 – 08/07/03	AdvaMed: PMA Submissions 101	Washington D.C., U.S.A. For more information: http://www.advamed.org/mtli/
08/10/03 – 08/14/03	NACDS Pharmacy Conference	San Diego Convention Center San Diego, California U.S.A. Contact: NACDS Meetings Department (703) 549-3001 Email: meeting_info@nacds.org www.nacds.org
08/14/03 – 08/18/03	International Conference & Exhibition of the Modernization of Chinese Medicine and Health Products	Hong Kong Convention and Exhibition Centre 1 Expo Drive, Wanchai, Hong Kong Contact information: Hong Kong Trade Development Council: http://www.icmcm.com/contact/contact.htm Exhibition website: http://www.icmcm.com/
08/20/03 – 08/21/03	AdvaMed: Design Control and Production and Process Control	Washington D.C., U.S.A. For more information: http://www.advamed.org/mtli/

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09/10/03 – 09/12/03	SCC Sunscreen Symposium	Grand Floridian Hotel Orlando, Florida, U.S.A. More info: Regina Lim (386) 239-8787 Email: regional@productquestmfg.com
09/10/03 – 09/13/03	Euro Fed Lipid: 1st European Symposium on Plant Lipids – From Fundamental Biology to Industrial and Field Applications	Aachen, Germany http://www.eurofedlipid.org/meetings/aachen/index.htm
09/12/03 – 09/15/03	Cosmoprof Cosmetica	São Paulo, Brazil More info: (39) 02-796-420 Email: sogecos@cosmoprof.com
09/13 – 09/15/03	16th Latin American and Iberian Cosmetic Congress	Cartagena de Indias Colombia More info: 57-2-45-99-32
09/15/03 – 09/16/03	Principles and Practices of US Regulatory Affairs	Holiday Inn Hotel & Suites Alexandria, Virginia U.S.A. More info: (301) 770-2920 Regulatory Affairs Professional Society Email: raps@raps.org http://www.raps.org/
09/17/03 – 09/19/03	Cosmeeting and Cosmatch	Exhibition Center Paris Nord Villepinte Paris, France More info: 33-1-44-699-555 Email: ann.france.mareine@cosmeeting.com http://www.cosmeeting.com
09/18/03 – 09/19/03	AdvaMed: Combination Products	Washington D.C., U.S.A. For more information: http://www.advamed.org/mtli/
09/22/03 – 09/24/03	IFSCC International Conference	Seoul, South Korea More info: (44) 1582 726661 Email: ifsc.sc@btinternet.com www.ifsc.org
09/30/03 – 10/02/03	HBA and CTFA: Personal Care Ingredients & Technology Expo	Jacob K. Javitz Convention Center New York, NY U.S.A. More info: Email jgonzalez@cmpprincipeton.com http://www.personalcareexpo.com/
10/19/03 – 10/22/03	RAPS 2003 Annual Conference & Exhibition	Baltimore Marriott Waterfront Hotel Baltimore, MD, US More info: (301) 770-2920 Regulatory Affairs Professional Society Email: raps@raps.org http://www.raps.org/
10/21/03	SCC California Suppliers Day	California, USA Contact: Brad Rope (310) 214-0043 ext. 40 Email: brope@bioscreen.com http://www.caliscc.org
10/22/03 – 10/25/03	Luxe Pack Monaco	Grimaldi Forum, Monaco More info: KX Associates (212) 925-2507

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11/11/03 – 11/12/03	SCS Formulate 2003 Conference and Exhibition	National Motorcycle Museum Birmingham, UK More info: 44-1-892-518877 Email: scsformulate@stepex.com
12/04/03 – 12/05/03	Society of Cosmetic Chemists Annual Meeting & Technology Showcase	New York Hilton and Towers Hotel New York, NY, U.S.A. More info: (212) 668-1500 Email: scc@scconline.org www.scconline.org
12/07/03 – 12/11/03	Consumer Specialty Products Association Annual Meeting	Marriott Harbor Beach Resort Fort Lauderdale, Florida, U.S.A. More info: (202) 872-8110
12/08/03 – 12/09/03	Regulatory Strategy Workshop	Hyatt Regency Coral Gables Coral Gables, Florida U.S.A. More info: (301) 770-2920 Regulatory Affairs Professional Society Email: raps@raps.org http://www.raps.org/

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FOOD & DRUG PRACTICE

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