

Natural Medicine Law™ Newsletter

JUDGE KESSLER HEARS SAW PALMETTO CLAIM

Judge Gladys Kessler of the U.S. District Court for the District of Columbia on October 28, 2002, heard oral arguments on plaintiffs' motion for summary judgment in *Whitaker, et al v. Shalala*, a case concerning the health claim for saw palmetto that reads "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia, and reduce voiding urgency associated with mild benign prostatic Hyperplasia (BPH)."

According to Jonathan Emord of Emord & Associates, the judge was very attentive and engaged in the discussion that took place. Emord told the court that the First Amendment requires the statute to be interpreted in its plain meaning and that there was no necessity to question its meaning since no member of Congress suggested any meaning other than the plain meaning that would be at odds with the plain meaning. The *Chevron* case test for meaning was the basis of this leg of the argument.

Emord argued that FDA's interpretation would prohibit the claim from being a health claim. FDA says BPH is a disease and Saw Palmetto has a pharmacologic effect. Emord said FDA interprets the claim as turning Saw Palmetto into a drug requiring an NDA. The economic evidence before the court demonstrated that an NDA would cost \$58 to \$200 million and this would require the makers of Saw Palmetto to become drug

See **SAW PALMETTO** -- on page 2...

FDA SEIZES SUPPLEMENTS WITH DRUG CLAIMS

At the request of the Food and Drug Administration (FDA), US Marshals seized dietary supplements making drug claims from the Humphrey Laboratories of Lake Oswego, Oregon, doing business as Kirkman Laboratories. U.S. Marshals seized hundreds of bottles of Kirkman's HypoAllergenic Taurine Capsules after FDA determined that these products made unsubstantiated claims to treat autism, a neurobehavioral disorder that begins in early childhood.

FDA seized these products because they violate the Federal Food, Drug, and Cosmetic Act. In accordance with the Act, all dietary supplement products' labeling must be truthful and not misleading and may not make any claims that the product will cure, mitigate, treat, or prevent disease. Consequently, the claims that the capsules treat autism caused the firm's product to be a misbranded food and an unapproved new drug.

"FDA will continue to pursue products that violate the law," said FDA Deputy Commissioner Dr. Lester M. Crawford. "This seizure emphasizes our commitment to protect the public health by keeping the marketplace free from products that make medical claims not substantiated by scientific evidence."

This seizure was the result of FDA's investigation of the firm's Internet site. To date no illnesses have been reported in association with consump-

See **TAURINE CAPSULES**-- on page ...2

NIH STUDIES COMPLEMENTARY AND ALTERNATIVE MEDICINE

The National Center for Complementary and Alternative Medicine (NCCAM) and 16 Federal co-sponsors announce the launch of an Institute of Medicine (IOM) study of the scientific and policy implications of the use of complementary and alternative medicine (CAM) by the American public. The \$1 million, nearly 2-year study, will be conducted by the IOM, a component of the National Academies.

The National Academies is a private, nonprofit, non-governmental institution created by a congressional charter to be an advisory body for the nation on scientific and technological matters. The IOM draws upon volunteer panels of experts to examine policy matters regarding the public's health. NCCAM, the primary sponsor of the study, is the Federal

See **NIH STUDIES CAM** -- on page 8...

In This Issue:

Judge Kessler Hears Saw Palmetto Claim.....	1
FDA Seizes Taurine Capsules.....	1
NIH Studies CAM.....	1
Citizens Petition on Kava.....	2
Joint Comments on First Amendment.....	3
Law Suit on Trade Secrets.....	3
Valerian Trademarks.....	3
Section 403 Letters.....	4
Lord Hunt Bucks Up Public.....	5
Story in <i>The Guardian</i>	5
Natural Products Expo East 2002.....	6
Phosphatidylserine Claim.....	9
New Dietary Ingredient Rulings.....	10
FDA's Crawford Testifies in U.S. Senate.....	13
Lloyd Library Photo Credits.....	15
Food Chemicals Codex Comments.....	18
FDA Action Plan on Acrylamide.....	18
New DRIs and the <i>Trans</i> Fat Fight.....	25
USP Seeks Comments on 14 Monographs.....	26
USP Announces Weider Joins DSVP.....	27
NNFA Plans GMP Program.....	27
Interesting Research.....	28
Classified Ads.....	28
Harvesting Health from the Editor.....	28

SAW PALMETTO -- from page 1...

companies to do studies that they could never recoup, since they could not patent the product.

The court questioned whether the *Western States* holding really applied and Emord said the Supreme Court decision in *Western States* (dealing with pharmacy compounding) was applicable by requiring that if a less speech restrictive alternative was available the health claim had to be processed.

According to *NML* sources, the FDA attorney replied that he had not read the *Western States* case and in general the government argument was one which simply assumed "It can be done. Maybe not by these plaintiffs, but it is possible to do an NDA." Emord described the government argument as vacuous and really not a choice.

Emord told *NML* that the *Pearson v. Shalala* case, the plain meaning of the health claim statute, and statements made by Congress during the floor debates made clear that members wanted the exception from drug approval to be a general one. The Court is expected to rule in the next three to six months. Readers can follow *Whitaker, et al v. Shalala*, Civil Action No. 99-3247 (GK) by stopping by the U.S. District Court or reading *NML*. Jonathan Emord can be reached at 202-466-6937.

TAURINE CAPSULES -- from page 1...

tion of this product. FDA will continue to identify and take appropriate enforcement actions against fraudulently marketed dietary supplement products that make unsubstantiated medical claims in their labeling. This information was issued October 17, 2002 by the FDA.

CITIZENS PETITION ON KAVA SUPPLEMENTS

Jarrow Formulas, Inc., of Los Angeles, California, submitted a citizens petition to FDA asking the agency to assert its exclusive jurisdiction with respect to warning labeling of Kava dietary supplements. The 19-page document was dated October 4, 2002 and given Docket No. 02P-0428 by the FDA Dockets Management Branch on October 8, 2002. James Prochnow, Esq. of Patton Boggs, LLP, at the firm's Denver, Colorado office filed the petition.

The petition says Jarrow sold kava containing products to retailers until March 15, 2002. The issue is "hot" according to the petition because a California trial court has been asked to issue an Order to mandate a special warning on labels and "shelf-talkers" on all kava products sold in California. Jarrow does not want a court deciding labeling issues and asks the FDA to get involved.

The local California case is *In Re Kava Litigation*, Los Angeles Superior Court, Consolidated Case # BC 269717. The Petition asks FDA to file a motion in the case to dismiss the plaintiffs' claims based on the doctrine of implied pre-emption, and the commerce clause of the United States Constitution as well as any other basis the FDA can assert. Jarrow asks FDA to assert all jurisdiction, beyond the California lawsuit, and when FDA's Kava studies are completed to either issue a Guidance Document or a Notice of Proposed Rulemaking to begin the regulatory process for labeling supported by sound science.

The Petition goes on to lay out a factual background about *Piper methysticum* that includes some historical information about the American Herbal Products Association in-

terest in Kava. For example, AHPA hired a board certified toxicologist to review all known adverse reports about Kava. Donald Wailer, Ph.D. reported in February 2002 that "based on currently available information, ... kava when taken in appropriate doses for reasonable periods of time has no scientifically established potential for causing liver damage." But he did say that taking some prescription drugs or alcohol with kava may be associated with liver damage or dysfunction.

By August 21, 2002, the Canadian government stopped the sale of kava citing its own safety assessment. But the FDA advised it had not changed its position in light of the Canadian action.

Legal grounds cited in the Petition are the Implied Pre-emption Doctrine discussed in *Gade v. National Solid Wastes Management Association*, 505 U.S. 88, 89, 98, 99, 112 S. Ct. 2374 (1992). Also cited was the Primary Jurisdiction issue that FDA has over labeling and warnings. The Petition said that without an official, national policy, there would be more lawsuits and inconsistent court rulings. On this point the Petition cited *Heller v. The Coca-Cola Co.*, 230 A.D.2d 768, 646 N.Y.S. 2d 524 (N.Y. App. Div. 1996). And the Petition said the Commerce Clause dictates a uniform policy according to several public policy articles citing one written by FDA's Chief Counsel Daniel Troy with Judge Robert H. Bork.

In California the case is actually a consolidation of three local cases filed by non-injured plaintiffs. The suits seek injunctions, corrective advertising, restitution, disgorgement of revenue, and attorney fees. On August 9, 2002, the Petition states that the Superior Court issued a stay in the

See KAVA PETITION -- on page 3...

KAVA PETITION-- *Continued from page 2...*
 case pending the FDA investigation.

Jarrow says the California lawsuit “cuts to the heart of DSHEA and undermines the role of FDA and its relationship to the dietary supplement industry...” Also, the lawsuit undercuts the Petitioner from having any dialogue with FDA as any statements made could be considered in the lawsuit to be construed as admissions against interest.

So far the American Botanical Council, the American Herbal Products Association and the Council on Responsible Nutrition have suggested three different sets of recommendations for labeling. FDA has also issued four separate announcements on kava. In other areas of public health and safety concerns, such as the prescribing of Prempro, the FDA has asserted its jurisdiction promptly.

**JOINT COMMENTS ON
 FIRST AMENDMENT FILED**

On September 13, 2002, Emord & Associates, on behalf of Julian M. Whitaker, M.D.; Durk Pearson and Sandy Shaw; Pure Encapsulations, Inc.; Wellness Lifestyles, Inc.; Suarez Corporation Industries; Life Enhancement Products; and Life Extension Foundation, responded to the FDA’s request for comments.

Those Joint Commentors evaluated all FDA speech regulations under applicable First Amendment standards. They found obvious, less speech-restrictive alternatives for each such regulation. They recommend either revocation or reform of the regulations that violate the free speech guarantee. They call for reform of FDA’s regulatory mindset on speech issues to favor disclosure over suppression of information. They supply FDA with

(1) new speech regulations that comply with the First Amendment and (2) a guidance for agency staff compelling adherence to legal limits on regulatory action. They recommend that no speech suppression be undertaken without advance First Amendment review and approval by the Office of the Chief Counsel.

An electronic copy of the comments can be retrieved from the Emord & Associates website at www.emord.com. Hard copies can be obtained by calling Katie Bond at (202) 466-6937. The Emord website PDF version is the best to read. FDA’s version is a PDF of an e-mail file that did not correctly translate to match the original file.

The submission is 159-pages long and has a table of contents that is two pages long. This grand-daddy submission covers most of the conceivable legal arguments and provides a lot of information to FDA. The submitters obviously hope FDA will pay close attention and speed its course to adopting the recommendations. Dkt. No. 02N-0209, EMC 158. September 18, 2002.

**SUIT FILED FOR
 TRADE SECRET**

Jerome Stevens Pharmaceuticals, filed a \$1.3 billion complaint against the FDA, HHS and the United States under the Tort Claims Act, Administrative Procedures Act and the Fifth Amendment for the unauthorized publication of its trade secrets and confidences. The complaint is filed in the U.S. District Court for the District of Columbia

In August 2000, Jerome Stevens became the first company to be granted approval for a stabilized version of levothyroxine sodium, a drug

used to treat thyroid ailments. That approval positioned the company to become a leader in the third largest drug market in the United States. After granting approval, however, FDA violated federal, civil and criminal law by posting on the FDA website a drug approval package that included Jerome’s trade secrets and confidences. In addition, FDA allowed other drug companies to continue to sell unapproved, unstable versions of levothyroxine sodium until 2003 despite finding significant health risks with those versions in 1997.

An electronic copy of the complaint can be retrieved from the Emord & Associates website at www.emord.com. Hard copies can be obtained by calling Katie Bond at (202) 466-6937.

VALERIAN TRADEMARKS

Once a pharmaceutical grade product made by companies like Eli Lilly & Co. and other companies for main line medical doctors in the last century, this sleep aid product is still popular among herbal and naturopathic practitioners. Here is the status of trademarks on file with the U.S. Patent and Trademark Office. There are nine marks, five of them still alive, and four dead. The live marks are reviewed first.

Valerian Plus® is a registered trademark on the Principal Register, Registration No. 2271980, of Amrion, Inc., a Colorado corporation in Boulder. The mark is for

See VALERIAN -- page 9.

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SECTION 403 LETTERS

More than 9,000 notices have been filed for structure/function claims or statements of nutritional support by the middle of September, 2002, and over 600 of these have received FDA Letters of Objection. Here are some more of the current “courtesy letters.”

Dee Cee Laboratories, Inc. of White House, Tennessee wrote FDA on July 23, 2002 to say it would be making claims for two products. The product Guggulextra #868 uses the claim “*Nutritionally Supports Healthy Cholesterol Levels.*” The product Beta Sitosterol#584 uses the claim “*Use as Part of Your Diet to Nutritionally Support Healthy Cholesterol Levels.*” FDA responded on August 12, 2002 to state that in the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. FDA said the claims for the products do not establish that the claims are about blood cholesterol levels that are already within normal limits and, therefore, imply that the product is intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease. The statements being made for these products suggest that they are intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. Dkt. No. 97S-0163, Ltr. 632.

Tabak’s Health Products of Costa Mesa, California wrote FDA on July 24, 2002 to advise that it is making the following claims, among others, for the product Glucosamine Sulfate: “*Do You Suffer From Joint Discomfort? Receive a Bottle of Glucosamine Sulfate and “48 Natural Breakthroughs that Relieve Arthritis Pain”... “Special report: “48 Natural Breakthroughs That Relieve Arthritis Pain.” Which shows you: Seven “must take” nutrients...Four “healthy” foods that*

arthritis sufferers should avoid like the plague.. .The three FREE best arthritis pain helpers.. .Four simple exercises that work wonders.. .Why Eskimos almost never get arthritis, and what we can learn from them.. and much, much more – yours FREE !” FDA responded on August 12, 2002 saying that 21 U.S.C. 343(r)(6) makes clear that

a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product in the context of the offer of the “special report,” to the extent that the report you are providing to customers describes the benefits of glucosamine sulfate for persons with arthritis, suggest that it is intended to treat, prevent, cure, or mitigate a disease, namely arthritis. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. Dkt. No. 97S-0163, Ltr. 633.

Herbmax, Inc. of Santa Fe Springs, California, wrote FDA through Crosslinks International, Inc., of Los Angeles, California on June 10, 2002 to give notice that Herbmax is making the following claims for the following products. The product, Yunnan Baiyao Ding, uses the claim “. . . *for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, as well as frost-bite.*” FDA responded August 26, 2002 and advised that this claim is a disease claim because it suggests that



Photo Courtesy of Lloyd Library and Museum

See SECTION 403 LETTERS -- page 11...

LORD HUNT BUCKS UP THE PUBLIC

The English Health Minister Lord Philip Hunt spoke on October 10, 2002 to boost the public confidence that will result from the regulation of traditional herbal medicines. At a meeting of the Medicines Control Agency (MCA) and representatives of the herbal industry, Hunt responded to the concerns of over-regulation that have arisen in recent months. Hunt said any regulation must be proportionate with the ultimate aim of protecting public health.

One of the concerns has been that a large number of products would fall outside the European Directive proposed definition of traditional use and would therefore become illegal. But the MCA said there would only be two or three cases out of 270 different herbal ingredients brought to the agency's attention.

Hunt told the group that MCA had shown data on combination herbs to two herbalists and asked for general comments. They told MCA that they envisaged that a herbalist could give a positive opinion on the combination's traditional use. The MCA had earlier said that registering single ingredient and combination products under the Directive would have a very wide potential.

The MCA has been instructed to press in Europe to give industry greater flexibility to take account of traditional usage from outside the EU and to make progress on a regulatory home for non-herbal traditional medicines. Hunt called for the dialogue to continue between MCA and the herbal sector. Hunt said he would "continue to take a close personal interest. As the Directive continues to make progress, the watchword will be a sensible, flexible interpretation, consisting with protecting the public health and meeting necessary legal requirements." More information is available from David Daley in the Department of Health Media Centre on 020 7210 5656.

STORY IN THE GUARDIAN SAYS SUPPLEMENTS NOT ALLOWED

EU legislation is being accused of removing natural medicines from the shelves. The National Association of Health Food Stores claimed that three-quarters of its members could go out of business. New product licenses

and investments in research will hurt small British supplement companies, Joanna Blythman predicted in an article in *The Guardian* on September 14, 2002.

Saying that UK, the Netherlands, and Ireland have a more permissive attitude towards supplements than other EU member states, and this approaches the US, Australian, New Zealand and Canadian attitude.

The Food Supplements Directive setting maximum levels for vitamins and minerals might set the levels at two to three times the RDA, which would liberalize the level in many countries, but severely limit it in the UK.

The "framework" directive will also result in millions of people having their supplements taken away. Sue Croft of the Consumers for Health Care Choices says the process will wipe hundreds of supplements off the shelf.

The Traditional Herbal Products Directive, saying these products can be sold only if they are shown to be safe and produced to high standards, which means licensing like drugs, costing thousands of pounds. The 30 year marketing rule, 15 years of which must be in Europe, will have dramatic effects on time barring products. For example, Black Cohosh has only been available in the UK for about 5 years, and it will become illegal.

The Novel Foods Directive, designed to control genetically modified foods and new, functional foods, is being applied to everything that sold under the food law. And a final attack on supplements is the tidying-up of the EU Medicines Directive, which will reclassify everything with a physiological effect as a medicine, and this will make everything sold in health food stores a medicine and therefore illegal. 95% of the budget of the MCA comes from license fees, so it is directly interested.

See EU SUPPLEMENTS -- on next page...



EU SUPPLEMENTS -- Continued from p. 5...

The entire article from *The Guardian* was still available for downloading at www.guardian.co.uk/weekend/story/0,3605,790733.00.html at press time. Much of the consumer interest in the UK is being informed by Consumers for Health Choice which is an independent consumer organization with 6,000 members in the UK, and over 250,000 supporters on its database. CHC is run by a board of Directors who are elected annually. CHC has offices in London and Brussels and works with similar organizations around Europe. For more information about this group go to: www.healthchoice.org.uk.

NATURAL PRODUCTS EXPO EAST 2002

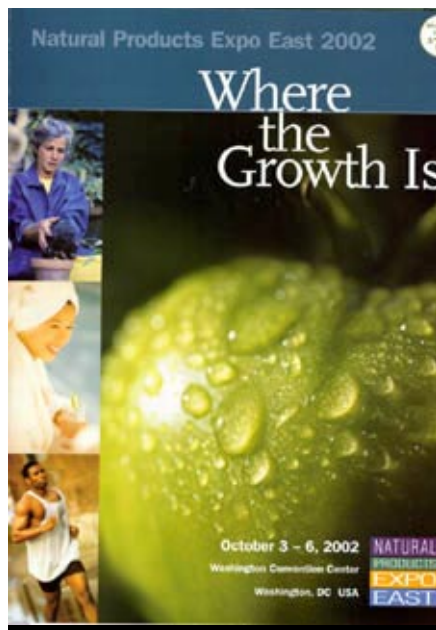
Another really big expo, this 2002 version in the Washington, D.C. Convention Center, was held on October 3 to 6. Many, many exhibitors had their new products and wares, nearly 20,000 thousands of retailers signed up at \$55 each and they spent three days looking at exhibits, some with models and scantily clad Adam and Eve, buying cases and cases of products, and attending educational programs. And, from the sound of some speakers, the masses visited their Congressman and Senators while they were in town. Everyone has ideas about why the law ought to be written one way or the other, but as all readers know by now, *NML* covers the legal issues primarily, so there is much that happened at this Expo that is not included in this article.

The program booklet for this event was 200 pages, chocked full of ads and information. There were three halls of exhibitors on the upper level and two more halls of exhibits on the

street level, consisting of thousands of new products, a total of 1,573 exhibitors in all. The post Expo release said that Fred Linder, president of the show producer New Hope Natural Media, a division of Penton Media, Inc., found that 63 countries were represented.

There was a specialty foods section for organic foods, products that are seeing large increases in sales. And there was a new Natural Living category this year with exhibits of organic clothing, shoes, organic gardening equipment, cleaning products, and home furnishings, like organic mattresses made of wool. Dietary supplements were all over the place.

One of the features of the exhibit area was the drawing for a new



Toyota Prius, a gas-electric hybrid auto, an entry for which could be had by visiting several exhibitors and getting a ballot signed off. Another drawing was for a three-wheeled covered vehicle. And there was a chip tasting event as well with many of the new organic snack chips offered for the attendees to taste.

According to the organizers there were buyers present from Costco, GNC, Safeway, Kroger, and King Soopers, and chains like Wild Oats and Whole Foods. Chinese, Japanese, Nepalese, Australians, Kenyans and many others were present to try to sell their wares. Some of these exhibitors were so “green” that they could only tell visitors they represented the government to sell products. After that statement they were lost in the sea of barter that went on with salesmen taking orders for cases and cases of products, others explaining how their products work, and many others just handing out samples, waiting for the taste of their specialities to snag a sale.

As *NML* visited the booths the focus was on health claims and treatment of disease claims that many of these products proclaimed on the exhibits and in literature. *NML* asked questions like, “When did FDA approve this product?” “What evidence do you have to support your claims on this brochure?” And “Does this product really do what you say?”

One exhibitor confesses that if the Food and Drug Administration or Federal Trade Commission were present, there would not be a booth that did not have a violation of some sort or another. When another exhibitor was asked if the product was approved by the FDA, the response was that that the MCA had referred them to the MDA – the English regulatory authority for medical devices. But they were promoting and selling anyway.

Over 45 on-site education programs were presented by speakers on a number of topics. More on

See NPEE 2002 -- on page 7...

NPEE 2002 -- from page 6...

these in a moment. Workshops were led by Thomas Perls, M.D., Associate Professor of Medicine, Harvard Medical School, ("Living to 100: Lessons in Living to your Maximum Potential at any Age), Jacob Teitelbaum, M.D., director of the Annapolis Center for Chronic Fatigue Syndrome/Fibromyalgia Therapies ("Nutritional Support for Chronic Fatigue") and Linda Nachtigale, M.D., director, Women's Endocrine Center, Saint Elizabeth Medical Center, Boston, MA ("HRT – What Now?").

A keynote speaker on October 4th was economic expert Jeremy Rifkin, founder/president of The Foundation on Economic Trends, who spoke about "Natural Products in the Biotech Century." And there was a Spirit of Organics Awards Dinner, sponsored by New Hope Media and the Organic Farming Research Foundation at which Senator Patrick Leahy (D-Vt.) was among the dignitaries honoring three of America's outstanding organic farm families at a sold-out event held at the National Museum of Women on the Arts on October 3rd.

The Organic Farming awards went to Phil and Katherine Foster of San Juan Bautista, CA, Klaus and Mary-Howell Martens of Penn Yan, N.Y. and Tom and Irene Frantzen of Nashua, Iowa. At the dinner Wild Oats presented a donation of \$82,500 to the Organic Farming Research Foundation, that was raised by a national 5% day in Wild Oats and Nature's stores across the country. The money will allow the OFRF to help local farmers become better producers. The Fosters farm 250 acres of certified organic land and sell their produce under the brand name

"Pinnacle" to local markets in northern California. The Martens have 1,000 certified organic acres in the Finger Lakes region of western New York where they raise mixed grains. Mary Howell teaches plant structure and function and serves on an Agricultural Biotechnology Advisory Committee for USDA and she writes for *Acres USA* magazine. The Frantzen's maintain about 100 organic pigs and raise organic soybeans, corn, barley and other crops on a 335 acre farm. They turned "organic" recently and began selling crops in 1998 and hogs in 1999.

NML saw some interesting products at the exhibits and heard some interesting lectures at the education sessions. Here is a summary of some of these experiences. Products for sexual arousal containing peppermint and other ingredients, enzymes products were sold for digestion and other purposes. Several hangover remedies and even more stop smoking remedies were present.

There were a large number of foreign products from Sweden, Australia, England, and African countries. There were some equipment manufacturers, such as L'Equip with a new series of juicers, blenders, and dehydrators, now out of LeMoyne, Pennsylvania. Alcodol is a hangover remedy to prevent or treat hangovers from BioRevive of Richmond, Victoria, Australia. B-Fresh Gum with 100% Xylitol from Rehoboth, Massachusetts' Global Sweet Polycols, LLC. The Leland Cherry Company of Leland, Michigan, was selling a concentrated Montmorency Cherry juice that contains melatonin, potassium, antioxidants, and anthocyanins. The product was recommended for relief of osteoarthritis and gout and its literature cites Dr. Russel Reiter of the

University of Texas Health Science Center.

Nasaleze was promoted for sneezing, runny nose, eczema itches, inflamed skin and to combat hayfever, eczema, asthma and allergies. When *NML* spoke to Mike James, the innovator of this product he indicated it was a natural product, methocellulose, ground to a fine form, and placed in a nasal injector. The literatures accompanying the product says James's theory is that mucous in the nasal tract attracts pollens and allergens, but when there is a lack of good quality mucous the overload of pollen and allergens causes this system to break down when mast cells (white blood cells located in the upper nasal tract) react with allergens by firing histamine into the surrounding tissue. This creates allergy symptoms, he thinks. When Nasaleze restores the protective mucous, the nasal track returns to full working order as a filter. This company in West Yorkshire, England has websites at www.nasaleze.com and www.HSIBaltimore.com.

There are a whole bunch of private label dietary supplement sellers at NPEE. The labels and labeling are very imaginative. Some companies have web sites, many do not.

Another category of exhibitors are the "cause" exhibitors, like the Roots of Appalachia Growers Association, helping to empower growers of native medicinal herbs in one section of the USA. RAGA works out of POB 21, Glouster, OH 45732.

And there is a 725-page guide, titled "Natural Products Field Manual 2002," on sale for \$2,499 or show

See NPEE 2002 -- on page 14...



Photo Courtesy of Lloyd Library and Museum

NIH STUDIES CAM - from page 1...

Government's lead agency for scientific research on CAM.

The IOM will assemble a panel of approximately 16 experts from a broad range of CAM and conventional disciplines, such as behavioral medicine, internal medicine, nursing, epidemiology, pharmacology, health care research and administration, and education. During the course of the study, the IOM panel will assess research findings, hold workshops, and invite speakers to address the panel, among other activities, in order to:

- Provide a comprehensive overview of the use of CAM therapies by the American public;
- Identify significant scientific and policy issues related to CAM research, regulation, integration, training, and certification; and
- Develop a conceptual framework to help guide decision-making on these issues and questions.

The value of undertaking this study emerged from discussions among

members of the Trans-Agency CAM Coordinating Committee, chaired by Stephen E. Straus, M.D., NCCAM Director. The Committee felt that the IOM had the expertise to critically consider questions of CAM research and policy.

“Americans use CAM therapies in record numbers,” said Dr. Straus. “The IOM’s report will give us a clearer understanding of the scope of CAM use by Americans, as well as CAM’s public health impact, and scientific and policy issues that will better inform our research decisions.”

The IOM study, led by Senior Program Officer Lyla M. Hernandez, MPH, of the Board on Health Promotion and Disease Prevention, will not conduct new surveys of the public regarding CAM use. Rather, the IOM panel will gather and analyze existing data. In addition, the IOM study, which will recruit panel members after October 1, plans to address many key questions, such as:

- What are the methodological difficulties in evaluating some CAM therapies?
- How are the different CAM professions regulated in the United States?
- What is the current situation for coverage of CAM by insurers and other third parties?
- What are the policy and regulatory issues regarding licensing and certifying CAM practitioners?

The answers to these questions and the information generated by the IOM panel of leading scholars drawn from both conventional medicine and CAM, and from education, should serve to complement the recommendations of the White House Commission on Complementary and Alternative Medicine Policy released ear-

lier this year.

The agencies that are co-sponsoring the IOM study include: Agency for Health Care Research and Quality, John E. Fogarty International Center, National Cancer Institute, National Center for Complementary and Alternative Medicine, National Center for Research Resources, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Child Health and Human Development, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute on Drug Abuse, National Institute of Mental Health, National Library of Medicine, Office of Behavioral and Social Sciences Research, NIH Office of Dietary Supplements.

For information on the National Academies, visit <<http://www.nationalacademies.org>>. For information on the Institute of Medicine, visit <<http://www.iom.edu>>.

The National Center for Complementary and Alternative Medicine (NCCAM) is dedicated to exploring complementary and alternative medical (CAM) practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals. For additional information, call NCCAM’s Clearinghouse toll free at 1-888-644-6226, or visit the

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VALERIAN-- Continued from page 3...

goods described as non-prescription dietary supplements and was first used on August 19, 1991. A disclaimer stating that "No claim is made to the exclusive right to use 'valerian' apart from the mark as shown" was part of the application. The mark was registered on August 24, 1999 and there is an assignment recorded.

Beyond Valerian® is a registered trademark on the Principal Register, Registration No. 2266234, of Makers of KAL, Inc., a Delaware corporation, operating in Park City, Utah. First use of the mark was claimed for February 1, 1999. The mark was registered on August 3, 1999 for goods described as dietary supplements containing valerian. There is a disclaimer in the application stating "No claim is made to the exclusive right to use 'valerian' apart from the mark as shown."

Valerian Evening® is a registered trademark on the Principal Register, Registration No. 2111361, of Natrol, Inc., of Chatsworth, California, and was first used in July 1996. The goods are described as herbal and dietary supplements. There is a disclaimer stating: "No claim is made to the exclusive right to use 'valerian' apart from the mark as shown." The mark was registered on November 4, 1997.

Valerian -Power® is a registered trademark on the Principal Register, Registration No. 1635929, of NaturPharma, Inc, of Orem, Utah, and the date of registration is February 26, 1991. First use is claimed for August 2, 1989 and there is no disclaimer. The goods described are Vitamin and Dietary Food Supplement. The mark is now owned by Twin Laboratories, Inc. of American

Fork, Utah in a recorded assignment, and the mark was renewed on May 31, 2001.

Valerian-Herbal® is a registered trademark on the Principal Register-2(F), Registration No. 1827162, of McZand Herbal, Inc. of Santa Monica, California, and was first used April 14, 1988 for goods described as dietary and nutritional supplement of valerian root. The registration date is March 22, 1994 and there is no disclaimer. A section 8 and section 15 affidavit was filed and acknowledged on May 13, 1999 and the company cites several prior registrations.

The dead marks include: **Valerian Root Xtra**, Serial No. 75451227, abandoned on December 9, 1999 by Rexall Sundown, Inc. of Boca Raton, Florida. The application claimed intent to use for Vitamins, minerals, dietary supplements all containing valerian root and the mark was published for opposition on March 16, 1999. Abandonment was ordered because no statement of use was filed after Notice of Allowance was issued.

Valerian Xtra, Serial No. 75451201, was abandoned March 11, 2001 by Rexall Sundown, Inc. of Boca Raton, Florida. The application claimed intent to use for goods described as Vitamins, minerals, dietary and nutritional supplements all containing Valerian Root. A disclaimer was filed in the application stating: "No claim is made to the exclusive right to use 'valerian root' apart from the mark as shown." The abandonment was ordered since no statement of use was filed after issuance of the Notice of Allowance.

Cayenne Valerian Plus, Serial No. 74496940, was abandoned July

11, 1994 by Heart Foods Company, Inc. of Minneapolis, Minnesota. The application was filed as an intent to use application for Herbal Encapsulated Product (herbs in capsules). The mark incorporated a heart design with the words stylized inside the heart. There was no disclaimer and the mark was abandoned at the express request of the applicant.

Cayenne Valerian Plus, Serial No. 74481776, was abandoned August 8, 1995 by Heart Foods Company, Inc. of Minneapolis, Minnesota. The application was filed as an intent to use application for Nutritional Supplements, namely capsules containing medicinal herbs. The mark incorporated a heart design with the words stylized inside the heart. There was a disclaimer stating: No claim is made to the exclusive right to use "Cayenne Valerian" apart from the mark as shown. The abandonment was ordered as no statement of use was filed after the Notice of Allowance was issued.

[Abandonments of intent to use applications can be the result of several issues, including the failure to market the product or an agreement with a potential opposer to not complete the application. Each file would need to be retrieved and reviewed to determine the exact reason for the abandonment. – Ed.]

PHOSPHATIDYLSERINE HEALTH CLAIM MOVES

Although the petition by Dr. Kyl Smith, a D.C. chiropractor, was filed in April, 2002 for health claims concerning phosphatidylserine and cognitive dysfunction, it is still trying to

See SMITH CLAIM -- on page 10...

SMITH CLAIM -- Continued from page 9...

get out of the starting gate. The model claims in the petition are stated as follows: “*The consumption of phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly*” and “*The consumption of phosphatidylserine may reduce the risk of dementia in the elderly.*”

What has happened since is that FDA Chief Counsel held a telephone conversation with Jonathan Emord, the counsel for Dr. Smith on or about July 12 and wrote to Emord on July 15 to propose a new deadline date of September 13. The FDA review period was to end on July 28 and at the time of the call, there were 16 days left in the mandatory review period. Emord agreed to the extension and a month later submitted certain information to show that phosphatidylserine was not a new dietary ingredient.

On September 13, Kathleen Ellwood, Ph.D., of the FDA Office of Nutrition Science and Policy wrote Emord to advise that if FDA does not respond within 90 days of the filing, the petition is deemed denied. FDA calculates the 90 day period to end on December 12, 2002.

NEW DIETARY INGREDIENT RULINGS

An August 16, 2002 notice was filed in the Dockets Management Branch concerning the new dietary ingredient submission by **Bioriginal Food & Science Corporation** of Saskatoon, Saskatchewan, for Echium Oil or Crossential SA14. The 75-day premarket notification period for this submission ended on November 13, 2001 as the file was received by FDA on August 15, 2001. The agency had written the company on August 23, 2001 to say that the submission does not comply with 21 CFR §190.6 and that several references have missing pages. In addition, some of the submission was in foreign languages without translation and some of the type is too small to read, the letter said. Therefore, because of incompleteness, FDA did not review the information, and told the company that it was welcome to submit additional evidence of safety information or a new notification.

Because the information did not provide a basis to conclude the product was safe under the conditions recommended in the labeling, the product may be adulterated under 21 U.S.C. 342(f)(1)(B). In that event, the product

is prohibited from being in interstate commerce under 21 U.S.C. 331(a) and (v). FDA said it would keep the letter confidential for 90 days and that the company could write to designate information that is proprietary. Dkt. No. 95S-0316, RPT 100.

Inter-Health Nutraceuticals, Inc. of Benicia, California, submitted a 75-day premarket notification on September 18, 2001 informing the FDA that it would market a new dietary supplement containing a new dietary ingredient “*trans-Resveratrol.*” This was described as the root extract of *Polygonum cupidatum*, Siebold & Zucc. with the tradename Protykin® (RSV-5000) powder that provides a standardized level of 50%. FDA responded on December 21, 2001 saying that a careful review of the submission indicates that the *trans-Resveratrol* is not a dietary supplement because it is an article authorized for investigation as a new drug. Citing studies at the Institute of Human Virology at the University of Maryland, previously published in a newsletter from that source, the agency said these studies are looking at its use in combination with nucleoside analogs in the treatment of immunodeficiency virus infections. FDA designated the ingredient as an investigational new drug on January 30, 2001. And the agency does not have any information that the ingredient was marketed prior to October 15, 1994, a condition of being a dietary supplement.

Also, FDA said it had concerns about the adequacy of the information about safety since the notification did not disclose the content of Protykin®, provide safety information on it, or demonstrate that its content of *trans-Resveratrol* has the same bioavailability as that found in wine and foods. Nothing identifies the other 50% of the product. FDA said that evidence was needed that long-term daily use is reasonably expected to be safe for the targeted consumers stated in the notification. Certain health concerns were not addresses at all, FDA said. For these reasons, the product may be adulterated and introduction into interstate commerce is prohibited. Dkt. No. 95S-0316, RPT 101.

PharmaSe, Inc. of Lubbock, Texas, submitted a 75-day premarket notification on December 21, 2001 for “L-Se-methylseleocysteine (SeMC)”. FDA responded on March 25, 2002 to advise that the information initially and in several earlier submissions was acceptable under

See NEW INGREDIENTS -- on page 18...

SECTION 403 LETTERS - Continued from page 4...

the product is intended to treat, prevent, or mitigate diseases, namely disorders such as arthritis and other conditions that result in pain. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. FDA stated that since pain is not a normal state, nor are there “normal pain levels,” a claim about pain treatment or prevention is ordinarily a disease claim. FDA addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. FDA added, however, that an acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise. But, the company’s claim includes no context that to limit the scope of the intended use of the product to non-disease states that result in pain and, in fact, the claim explicitly states that it is intended to treat pain associated with diseases such as arthritis, backache, strains, bruises, and frostbite. The company also submitted a notification for the product, Liuwei Dihuang Wan, that states that this product is “...for people with...tinnitus...” FDA also advised that 21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that the company makes for these products suggests that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. Finally, FDA said that the representation that the product Yunnan Baiyao Ding “...is used as oral administration or externally...” This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, cannot be marketed as a dietary supplement. The claim to use this product externally is a claim that describes an effect of the product that is not achieved by its ingestion. Therefore, the product does not meet all of the elements of the statutory definition of a dietary supplement, namely that it be a product

intended for ingestion, when it is intended to be applied to the skin. This product is not “intended for ingestion.” As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product “intended for ingestion.” The term “ingestion” has been addressed by the court in *United States v. Ten Cartons. Ener-B Nasal Gel*, 888 F. Supp. 381,393-94 (E.D.N.Y.), aff’d, 72 F.3d 285 (2d cir. 1995). The interpretation of the term “ingestion” to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) “only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure.” This elaboration of “liquid form” also denotes ingestion by swallowing the fluid. Therefore, because the term “ingestion” means introduced into the gastrointestinal tract, a product that is used to deliver its ingredients into the body when applied topically to the skin is not subject to regulation as a dietary supplement because it is not “intended for ingestion” because it is intended for external or topical use. Moreover, this product may be subject to regulation as a drug under the Act. Dkt. No. 97S-0163, Ltr. 634.

Metagenics of San Clemente, California wrote FDA on July 31, 2002 to give notice that the product Meta-Sitosterol uses the claim “...may help to maintain healthy blood cholesterol levels by interfering with the absorption of dietary cholesterol from the digestive tract.” FDA responded on August 26, 2002 that the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. FDA stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product does not establish that the claim is

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Continued on page 12...



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SECTION 403 LETTERS -- from page 11...

about blood cholesterol levels that are already within normal limits and, therefore, implies that the product is intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease. The statement that the company is making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. Dkt. No. 97S-0163, Ltr. 635.

Pharmavite Corporation of Mission Hills, California gave notice to FDA on July 30, 2002 several products. The product Cholest-Off™ uses the claims “Cholesterol Fighter” and “Clinically proven to lower LDL cholesterol up to 24%,” among other claims. FDA responded on August 26, 2002 that the statements

being made for this product are statements about the relationship between plant sterols and stanols and the risk of coronary artery disease and are not claims subject to 21 U.S.C. 343(r)(6), but instead are claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between plant sterol esters and stanol esters and the risk of coronary artery disease (see 21 CFR 101.83). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between plant sterol esters and stanol esters and the risk of coronary artery disease in its labeling. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.83 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.83 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary artery disease. For several reasons, this product does not appear to meet the eligibility requirements to bear the health claim authorized in 21 CFR 101.83 in its labeling. Furthermore, the claims themselves do not appear to meet the message requirements set forth in the regulation. The product does not appear to contain plant sterol or stanol esters. Instead, it contains Reducol™, an ingredient that the claims make clear contains only unesterified plant sterols and unesterified plant stanols. These ingredients do not qualify a product containing them to bear the authorized health claim in its labeling. Moreover, even if the product contained ingredients covered by 21 CFR 101.83, the amounts provided

per serving of Reducol™ do not meet the eligibility requirement in 21 CFR 101.83(c)(2)(i)(G) and (H). Additionally, the claims made for the product do not meet the message requirements in the regulation. For example, the statements for Reducol™ do not state that the product “may” or “might” reduce the risk of heart disease (21 CFR 101.83(c)(2)(i)(B)); in fact, no where in the claim being made for your product are the terms “heart disease” or “coronary heart disease” used. Therefore, since your statements are not claims under 21 U.S.C. 343(r)(6) and are also not authorized health claims under 21 U.S.C. 343(r)(1)(B), they are claims that suggest that this product is intended to treat, prevent, cure, or mitigate a disease, namely coronary artery disease. These claims suggest that this product is intended for use as a drug within the meaning of 21 USC. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. The product, Diabetes Health Pack, uses the claims “May help maintain blood glucose levels..” (for selenium) and “may help maintain glucose metabolism” (for alpha lipoic acid). These statements, rather than being statements about the product being intended to meet the dietary needs of persons with diabetes, are instead statements that represent the product to be intended to treat the characteristic sign or symptom of diabetes, namely, the inability of persons with diabetes to metabolize glucose effectively. These statements are not claims under 21 U.S.C. 343(r)(6) but rather they are claims that suggest that this product is intended to treat, prevent, cure, or mitigate a disease, namely diabetes. These claims suggest that this product is intended for use as a drug within

Continued on page 13...

SECTION 403 LETTERS -- from page 12...

the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. The product, SAM-e, uses the claim “*Joint Pain Relief*” and “*Relieves joint pain by helping to repair and maintain joint cartilage which naturally deteriorates with physical activity and age.*” These claims are disease claims because they suggest that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that “joint pain” is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. FDA stated that since pain is not a normal state, nor are there “normal pain levels,” a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. FDA added, however, that an acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise. The claim contained in your notification refers to pain associated with changes in cartilage associate with aging and physical activity. While cartilage

changes associated with physical activity and age may not in themselves be diseases, such changes would not be expected to result in joint pain unless a person already suffered from an underlying disease or such changes were so extensive as to constitute a disease itself, which in turn predisposed him or her to such pain. 21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. Dkt. No. 97S-0163, Ltr. 636.

FDA’S CRAWFORD TESTIFIES TO UNITED STATES SENATE

On October 8, 2002, Lester M. Crawford, acting Commissioner of FDA testified in the Committee on Governmental Affairs of the U. S. Senate on the Regulatory Framework under DSHEA of 1994. Here is a summary of the topics he touched on. The full statement is available on the FDA website at www.fda.gov.

Crawford said the Framework’s purpose was to strike the right balance between providing consumers access to dietary supplements that they use to help maintain and improve their health and giving the FDA the necessary regulatory authority to take action against supplements that present safety problems, have false or misleading claims, or are otherwise adulterated or misbranded. Crawford said that the DSHEA regulatory framework for dietary supplements is primarily a post-market program, as is the case for

foods in general. Should safety problems arise after marketing, the adulteration provisions of the statute come into play.

He reminded the Committee that a dietary supplement is adulterated if, among other things, it or any of its ingredients presents “a significant or unreasonable risk of illness or injury” when used as directed on the label, or under normal conditions of use if there are no directions. FDA bears the burden of proof to show that a product or ingredient presents such a risk. In addition, the Secretary of Health and Human Services (HHS) has the authority to declare that a dietary supplement or dietary ingredient poses an “imminent hazard” to public health or safety.

FDA previously detailed its implementation guidance, in May 2002, by providing Congress with a “Dietary Supplement Strategic Plan Cost Out.”

THE DIETARY SUPPLEMENT—EPHEDRA — The testimony focus of this hearing was on ephedra. Ma huang is one of several names for herbal products containing members of the genus *Ephedra*. Adverse events related to these products are currently under investigation.

FDA Advisory Committees - 1995-1996 — In 1995, FDA convened a Working Group of the Food Advisory Committee Meeting on ephedra. They reviewed all the safety information available, including the known published literature on pharmacological issues and adverse event reports submitted to the Agency. This was followed in August 1996 by a meeting of FDA’s Food Advisory Committee. The prevailing view coming out of these meetings was that FDA should seek to establish a safe dose for ephedra products.

FDA Proposed Rule - June 4, 1997 — On June 4, 1997, FDA published a proposed rule on dietary supplements containing ephedrine alkaloids. Under the proposed rule, a dietary supplement would be adulterated if it contained eight milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggested or recommended conditions of use that would result in an intake of eight mg or more within a six-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids. FDA

See CRAWFORD -- on page 22...

NPEE 2002-- Continued from page 7...

price of \$1,999, that tells you everything you need to know to go to the market with a new product. This one is shown on www.NPCInstitute.com.

American Healthcare of Fairfield, New Jersey, sells Oly Gel, a new product with claims of being anti-swelling, anti-inflammatory, and pain relieving, that contains 1% Sodium Aescinate from the Horse Chestnut Tree and diethylamine salicylate 5%. It is sold in a 2 oz. tube.

Chaser, a dietary supplement of natural origin, according to the labeling, is represented as giving "Freedom from Hangovers." "Helps prevent headaches and other discomforts by absorbing harmful elements in beer, wine, and liquor." These 480 mg red caplets contain activated calcium carbonate 615 mg, vegetable carbon 345 mg, and some none active ingredients.

The Swiss company Olbas operates out of Philadelphia, Pennsylvania, with a group of products, Olbas Oil, Olbas Inhaler, Olbas Pastilles, Olbas Cough Syrup, Olbas Herbal Bath, Olbas Analgesic Salve, and Olbas Sport. The literature says the company is over 100 years old.

Olivenol™ containing polyphenols from the pulp of organic olives is a product sold by CreAgri, Inc. of Hayward, California. The product comes in vegetarian caps, tablets and vegetarian liquid forms. Hydroxytyrosol (HidroX™) is the principal natural ingredient. The labeling says scientific research indicates that polyphenols help fight free radical damage and help proved: cardiovascular wellness, colon & breast health, skin wellness, immune system balance, reduction of oxidative stress & cholesterol; and anti-microbial activity.

Another interesting product line are the several products from Tea Tree Therapy of Ventura, California. The company sells an oil, a shampoo, a conditioner, a hand & body lotion, an antiseptic cream, a liquid soap, a vegetable soap, a toothpaste, a whitening toothpaste, a baking soda toothpaste, a mouthwash and suppositories. For more information write e-mail to: teatree@pacbell.net.

In the category of educational products, here is one worthy of taking a look at soon. Paul R. Thomas, Ed.D., R.D. founded The Dietary Supplement™ a newsletter published six times a year, 16 pages each, all about dietary supplements. Cost is only \$32 per year and he DOES NOT cover the legal issues. What I saw was

about the "informed use of dietary supplements." Contact him at www.TheDietarySupplement.com.

Author Roger Mason was giving away copies of his 2002 book, 100-pages, *Zen Macrobiotics for Americans*, as his effort to get people acquainted with the subject. He works out of Wilmington, North Carolina with a line of products called Young Again. The book was published by Safe Goods Publishing in Sheffield, Massachusetts.

Many other products were displayed. You will have to come see for yourself.

The educational programs offered some interesting subjects this year as in the past. Here is a sample. One forward looking session was titled: "New Ingredients and Supplements with Potential," presenting five speakers – Loren Israelsen, Thomas Aarts, Dierdre Allen, Greg Stephens, and Roy Upton. Israelsen, introduced as the industry's zen master, said that there needs to be some disturbing thinking in the industry. Trends in food politics are described in Marian Nestle's book — "Food Politics" are extraordinary illuminating. She is not a friend to dietary supplements. In the last six months, the obesity situation has received focus with lawsuits against fast food chains and new data on the extent of obesity among the U.S. population. Outsiders are saying there is nothing for sale in your industry, "What is it you are selling?" Dietary supplements is large category and politicians on Capitol Hill are now asking if the category is too large. If politics changes and some new chairman hold hearings, the industry will face tough questioning, he said.

Tom Aarts of the *Natural Business Journal* sees the picture from on high, Israelsen said. Aarts said corporate nutritionists are more and more working on functional foods. In the next five years the association of health care costs and diet will become more important. Obesity is but one example where the statistics are staggering. It costs \$117 billion a year in health care costs, 300,000 deaths a year, 27% of the population is clinically obese, and from 1991 to 1998 the number of states with obese people increased dramatically. We are headed for a crisis in Medicare, insurance companies are backing out of the program. The \$53 billion natural personal care industry consists of functional foods (36%), natural organic foods (21%), and supplements (35%) with some in cosmeceuticals. Growth rates by products from

Continued on next page...

NPEE 2002- Continued from page 14...

2000 to 2001 are functional foods (7.3%), natural/organic foods (8.5%) most of this in organic foods.

Retail in the mass markets includes most of the functional foods. The entire category of organic food is moving into the mass market shopping places, with it growing 2% of the entire food industry, growing at a 10% plus growth rate for the last couple of years. It will become a larger part of the food industry, splitting into 87% organic and 11% natural. By 2010 the \$10 billion market will be closer to \$16 to 17 billion. The organic portion of the food industry will increase to about \$20 billion by then.

Herbal products are depressed and sometimes negative. They have been the darling and the bane of the industry. Specialty categories are going to increase. There is no big growth supplement. There is some growth in calcium. Supplements represent 6% of the overall OTC – prescription market.

The \$503 billion food industry is under pressure, Aarts said. The pharmaceutical industry is also under a lot of pressure. The functional food area is \$18.5 billion in 2001. The dietary supplement industry is \$17 billion. Over the next 10 years a much larger percent of the food industry will become functional foods. Functional foods are growing five times as fast as the food industry, so they will become a larger piece of the pie. Pepsico is leading the charge and 30% of the sales come from 5 companies.

Natural personal care products with cosmeceuticals – science based products for the skin – like Dr. Perricone’s “Wrinkle Cure,” are taking hold in the market. This area is growing at 9% and the category is 6% of the total. The health care industry is getting into the prevention mode because of consumer demand and economics.

The industry is now trying to define “functional foods,” but it basically is food to which ingredients have been added, like orange juice with calcium. Some companies have overspent trying to bring dietary supplements to market and they are not focusing on the functional food industry. This will require GRAS affirmations to FDA. A basic cost of this is \$100,000 and six months time.

Greg Stephens is from the medical food area of the pharmaceutical industry. These new products have health claims. Lipids and fiber products are growth areas. The

Food and Nutrition Board’s new DRIs (Dietary Reference Intakes) focus on supporting good health and reducing the risk of chronic diseases and minimizing the possibility of over consumption. Lipids are getting enhanced consumer awareness of good and bad fats. Alpha linoleic and others now have DRIs for the first time.

DHA and ARA in infant formulas has become more prevalent. Products have gotten more expensive but sales are increasing. EPA containing products for patients with cancer are increasing sales.

New facts on fiber include increased risk for cardiovascular disease in low fiber diets. The relationship between fiber, cancer and weight control is inconclusive, but the recommended intake is 38 Gm a day. The average U.S. adult gets about 12 Gm a day. Meeting this recommendation will require products. New definitions of fiber — Dietary fibers are non-digestible from food products. Functional fibers may be extracted. Total fiber content is the sum of the two. There will be more research on the fiber area.

3 Gm of oat fiber have a health claim to help prevent heart problems. \$50 million in advertising is spent each year promoting this. A new concentrated Beta-glucan is being demonstrated in studies. If a concentrated product can be made this will be a convenience to consumers.

EPA and CLA have an opportunities to grow. SAM-e will get a boost in November when new studies are

See NPEE 2002 -- on page 16...

PHOTOGRAPHS FROM LLOYD LIBRARY AND MUSEUM

Page 4 - Goldenseal (*Hydrastis canadensis*) from AMERICAN MEDICINAL PLANTS by Charles F. Millsbaugh, M.D. 1887

Page 8 - Valerian (*Valeriana officinalis*) from MEDICAL BOTANY by John Stephenson, M.D. and James Morss Churchill, F.L.S. 1829

Page 12 - Ginseng (*Panax quinquefolium*) from THE FAMILY FLORA AND MATERIA MEDICA BOTANICA by Peter P. Good 1847

Page 16 - Evening Primrose (*Oenothera biennis*) from AMERICAN MEDICINAL PLANTS, *supra*, 1887

NPEE 2002 - Continued from p. 15..

published by the *American Journal of Clinical Nutrition*. The potato enzymes that are ACE inhibitors will get more attention also.

There are 12 health claims for foods. (see list of approved Health Claims in the September 2002 issue of *Natural Medicine Law™ Newsletter* or search for this on FDA's website.)

Dierdre Allen spoke briefly about essential oil therapy and traditional Chinese medicine. Dr. Ann Wong at Harvard is attempting to get some American institution to receive live transmissions of Chinese lectures from TCM schools. In the U.S. we have exercised an arrogant method of taking one ingredient from a Chinese remedy, isolating it and presuming it is the active ingredient. We know so little about the differences in plants that "we are not grownup enough to deal with Chinese products."

Audiences were taken back last week at a food company conference at her slide showing how chemical toxins in the air and rise in obesity. The EPA website identifies new carcinogens that are measured in plasma levels. EPA even says this one affects the adrenal glands, this one the thyroid. Johns Hopkins is studying heavy metal toxicity and obesity. This is an area we have to get back to quickly.

Roy Upton is the conscience of the industry and a balanced forecaster according to Israelsen. Speaking about the botanical world, there is a new direction in health care for prevention, more than disease treatment. The Nutritional Education and Labeling Act of 1990 is starting to sink in now and modern medicine is begin-

ning to use concepts in nutrition to optimize health. This is the first time this shift has taken place. In Upton's crystal ball, he said we will see more botanical antioxidants in use and super foods that are rich in antioxidants such as blue berries and bilberries. Other tonics that will come on in the future is cordyseps that comes from a fungus product. Another growth area will be coming from the health professionals prescribing supplements and botanicals. Hospitals are attempting to determine how to prescribe these products and this will lead to insurance reimbursement. Once that happens there will be a fantastic boom. Specific legislation to reimburse for some products is being introduced. NCCAM research will bring on use of more botanicals. Upton predicted that Hawthorne would be substituted for digoxin in the future since it lengthens the ERP of the heart and is more safe.

Botanical immune tonics used in traditional Chinese medicine will increase in the next ten years, Upton predicted. U.S. treatment strategy has been on killing the cancer or cutting it out. The immune stimulation will help increase or maximize potential for quality of life and survival rates. Ricci mushroom, astragulas, schizandra, and others are used.

In another program featuring Gary Fulcher and James Prochnow, Esq., the new Oat Bran Concentrate was reviewed. This program is significant for readers to understand the process of FDA approval for such products. H. Griffith Parker, the CEO of Nuture, a 10-year old oats product company, said oats contain Beta Glucan. Oat products need to have claims that consumers will read to decide whether to buy, and there needs to be products that work.



Photo Courtesy of Lloyd Library and Museum

Adults are concerned about cholesterol and people are looking for nutritional solutions to help this problem.

Under DSHEA there are concerns about making claims that the product works on heart health. \$50 million is spent each year on advertising about the links of oats and heart health, so that 52 % of people think that oats helps heart health. Nuture, Inc.'s product is concentrated OatVantage™. 1.5 gm of it delivers 0.75 gm of beta-glucan. 79 % of adults are concerned about cholesterol. There is an \$18 billion market out there.

Since 62% are looking for nutritional products to help heart health. Quaker Oats started the interest in oats many years ago.

Gary Fulcher is from the University of Minnesota [NML reported on the expanded claims in Vol. 5, Issue,

See NPEE 2002 -- on next page...

NPEE 2002-- from page 16...

5, 2002, March 2002] Fulcher said that oat consumption has been declining for several years. Oat growers want to sell more. A closer look at oat kernels, shows β -glucans in the endosperm. Mixed linkage β -glucans are hooked up differently and this makes it totally different from anything in the market. Is it unique? Absolutely, Fulcher says.

Cereal materials are very different from other materials that one comes across. The physiological effect, the sticky dropping syndrome in chicken coops demonstrates that it is not soluble. The real reason that we are talking about β -glucans, is that it has activities. We see some immunological effects that cannot be discussed. β -glucans is a very thick material in the gut that increases viscosity that exerts a significant influence. β -glucans is not digested until it gets to the colon. Reduced cholesterol has been a result of increased viscosity in the gut.

Fulcher said, Jim Anderson in Kentucky is making some good progress in this area. Keenan's meta-analysis allowed some strong statements on β -glucans. Glycemic response is important.

He indicated that in hamster studies the results reduced cholesterol and he was working on a six-week human study as well. Glycemic response and immune responses will probably be confirmed again. Obesity and diabetes problems will need some solution. The alpha-link in starch is easily digested, the beta-link is not. Fulcher is working on solving these problems.

Jim Prochnow, Esq. of Arent Fox,

a Washington, D.C. law firm, spoke about the health claim connecting oats with reduction of cardiovascular disease. He spoke about GRAS and food additives, health claims, dietary supplements and conventional foods.

Not everything is applicable to dietary supplements. GRAS is not applicable to dietary supplements. Prochnow has been involved in food for 12 years, previously was with the Justice Department in Washington, D.C. He is from Colorado, but works out of Los Angeles.

Dietary supplements and foods can both use β -glucans as a component. NLEA of 1990 allowed health claims. DSHEA deals with dietary supplements. NLEA deals with ordinary foods. Health claims can be made on both types of products. The rule on β -glucans was promulgated in January 1997. The whole oats rule started with a petition filed by Quaker Oats in 1995.

The statute and the regulations are the primary things we have to look at. A final rule is published in the Federal Register and FDA includes its interpretation of that rule that led to the issuance of that rule. Those pages are an important resource to look at.

In 21 C.F.R. the rule is that soluble fiber added to diets may reduce the risk of heart disease. Structure/function claims can say more, but for dietary supplements you cannot link the supplement to a disease. "Supports heart health" would be an acceptable claim. A health claim is an exception that allows a health claim to be linked to a disease. To make the health claim you have to meet certain criteria in the regulation. For a structure/function claim, you do not have

to meet other criteria. You can only make a claim that links disease if it is an approved health claim.

On October 2, the FDA amended the rule to allow another source of β -glucans. A one-page regulation has 45 pages of explanation in this case. A health claim must meet the general regulations and the specific – which are that you can only use the words "may" or "might." Second you can use "CHD" or "heart disease." You cannot say it is a high reduction in cholesterol. And there are other rules to follow. β -glucans now can be from four sources, including the newest.

Oat bran is reviewed specifically, and a company must have in its possession certain information to make the claim. Other companies do not have to file the information once FDA has approved the claim. FDA said it would give the opportunity to tell the public about the product, i.e., you can talk about family history, or tell how it works in the body. You can use the facts set forth in the FDA rule, Prochnow said.

Model claims are set forth in the regulation, but if you include the basics you can tell the public the benefits of β -glucans in heart health. Health claims are more aggressive than structure/function claims, according to Prochnow.

GRAS becomes important because Generally Recognized As Safe must be complied with either in house or by filing data with FDA. A food additive can be petitioned to be approved by FDA. But if scientists generally agree that the product is safe, no GRAS application is required. [A company keeps the scientific facts in

See NPEE 2002 - on page 18..

NPEE 2002-- Continued from page 17...

their own files for substantiation when requested by FDA or even by FTC. – Ed.] For a supplement, the product needs to be a dietary ingredient. For a health claim for an ingredient added to a conventional food, it must be a food additive or GRAS. A food additive does not have to be proved as safe.

The producers of β -glucans can relate to consumers the use of them in the levels in the claim will reduce cardiovascular disease. Readers can find out more about the claims from www.oatvantage.com.

NEW INGREDIENTS -- from page 10 ...

certain conditions for using the ingredient at the level of 200 mcg Se/day. Some of the conditions were to exclude persons with renal problems unless qualified health care provider advises its use, and to exclude pregnant and lactating women unless additional information is submitted. The 90-day date for the submission was April 9, 2002, and FDA kept the file confidential until notifying the Dockets Management Branch on September 6, 2002 of its correspondence. Dkt. No. 95S-0316, RPT 112.

FOOD CHEMICALS CODEX COMMENTS

By contract with the Institute of Medicine (IOM) of the National Academies, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, the IOM issues a public announcement inviting all interested parties to comment on proposed new monographs and changes to existing monographs.

The IOM Committee on Food Chemicals Codex is in the process of revising the entire fourth edition of the Food Chemicals Codex and its supplements to produce a comprehensive fifth edition, scheduled for publication in the fall of 2003. FDA is giving notice that the committee is currently soliciting comments and information on a number of proposed new Food Chemicals Codex specification monographs and on proposed changes to certain monographs, as well as comments and information on any other item in the fourth edition of the Food Chemicals Codex or its supplements. For comments to be considered for the fifth edition of the Food Chemicals Co-

dex, they must be received by the committee by November 15, 2002. Comments received after November 15, 2002 may be considered for the first supplement to the fifth edition of the Food Chemicals Codex.

Copies of the proposed items may be obtained upon written request from the Committee on Food Chemicals Codex/TNA-728, Food and Nutrition Board, Institute of Medicine, 500 Fifth Street, NW, Washington, DC 20001 or through the Internet at <http://www.iom.edu/fcc>. Interested parties are encouraged to check this website frequently because the list of proposed additions and changes is expected to be updated several times over the next few weeks.

For further information, contact : Ricardo Molins, Project Director/TNA-728, Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine, 500 Fifth Street, NW, Washington, DC 20001, 202-334-2580; or Daniel Folmer, FCC Project Officer, Office of Food Additive Safety, HFS-265, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 202-208-3148.

FDA ACTION PLAN FOR ACRYLAMIDE IN FOOD

On September 20, 2002, FDA announced its draft action plan for acrylamide in food. A meeting was held with a large group of people representing most areas of the affected industries and public interest groups. The final plan is not yet complete. The draft action plan outlined FDA's goals and planned actions on the issue of acrylamide in food and includes a timeline of planned meetings. It also discusses FDA's intentions to work with other federal agencies and to participate in international efforts. This action plan will guide FDA's activities on the issue of acrylamide over the next several years. FDA will make the plan available on the CFSAN website. Follow-up discussions will occur at a Food Advisory Committee subcommittee meeting in December 2002, and a full Food Advisory Committee meeting in February or March 2003. The draft action plan is a working document, and FDA will revise the plan, as needed, based on public comment from these meetings and on knowledge gained from research developments.

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Background

On April 24, 2002, researchers at the Swedish National Food Administration and Stockholm University reported finding the chemical acrylamide in a variety of fried and oven-baked foods. The initial Swedish research indicates that acrylamide formation is particularly associated with traditional high temperature cooking processes for certain carbohydrate-rich foods. Since the Swedish report, similar findings have been reported by Norway, the United Kingdom, and Switzerland. Preliminary analysis by the FDA suggests that U.S. results will be in basic agreement with these findings. The discovery of acrylamide in foods is a concern because acrylamide is a potential human carcinogen and genotoxicant.

Mechanism

Acrylamide appears to form as a byproduct of high-temperature cooking processes (greater than 120°C or 248°F). It does not appear to be present in food before cooking. Research to date suggests that acrylamide formation is particularly likely in carbohydrate-rich foods. However, tests on carbohydrate-rich foods cooked at lower temperatures (e.g., by boiling) have shown much lower acrylamide levels. At this time, not enough is known about acrylamide formation to identify safe modifications to food processing techniques that will clearly prevent or reduce formation. Identifying mechanisms of formation will ultimately be an important step in identifying ways to reduce or prevent acrylamide formation during cooking.

Toxicology

There are uncertainties about the impact of acrylamide on public health. People have been eating some of the foods now reported to contain acrylamide for many years. To better assess the risk of acrylamide, more information is needed regarding which foods acrylamide is formed in, levels of acrylamide in foods, dietary exposure to acrylamide, the bioavailability of acrylamide in food, the potential of acrylamide to cause cancer when consumed in food, acrylamide's potential to cause germ cell mutations, and biomarkers of acrylamide exposure.

Acrylamide causes cancer in laboratory animals. As a result, acrylamide is considered a potential human carcinogen. However, it is not clear whether acrylamide causes cancer in humans. Scientists have conducted epidemiological studies of people exposed to acrylamide in the workplace. The studies did not show increased cancer risk with acrylamide exposure. However, these stud-

ies do not rule out the possibility that acrylamide in food can cause cancer, both because of the limited number of people in the studies and because the route of exposure for the workers was not through food.

WHO/FAO Recommendations

In June 2002, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) convened an expert consultation on acrylamide. The consultation, which was attended by three FDA experts, concluded that the presence of acrylamide in food is a major concern, and recommended more research on mechanisms of formation and toxicity. Both the WHO/FAO consultation and the FDA have recommended that people continue to eat a balanced diet rich in fruits and vegetables. The WHO/FAO consultation advised that food should not be cooked excessively, i.e., for too long or at too high a temperature, but also advised that it is important to cook all food thoroughly—particularly meat and meat products—to destroy foodborne pathogens (bacteria, viruses, etc.) that might be present.

FDA's Goals and Actions on the Issue of Acrylamide in Foods

Addressing the issue of acrylamide in foods will require research and activity on multiple fronts. Planned and current actions by the FDA include assessing the dietary exposure of U.S. consumers to acrylamide, gathering new information about the toxicology of acrylamide, and participating in the development of techniques for reducing acrylamide formation. As more data become available on acrylamide, FDA will continue to develop public health messages and regulatory options.

1. Major goals

- ♦ Assess the dietary exposure of U.S. consumers to acrylamide by measuring acrylamide levels in various foods.
- ♦ Develop rapid screening methods and validate confirmatory methods of analysis.
- ♦ Assess the potential risks associated with acrylamide in foods by extensive evaluation of the available information and by expanding research into

See Acrylamide-- on page 20...

www.NatMedLaw.com

Acrylamide -- Continued from page 19...

acrylamide toxicology.

- ♦ With partners, identify mechanisms responsible for the formation of acrylamide in foods and identify means to reduce acrylamide exposure.
- ♦ Inform and educate consumers and processors about the potential risks throughout the assessment process and as knowledge is gained.
- ♦ Develop and foster public/private partnerships to gather scientific and technological information and data for assessing the human risk.

2. Actions

Development of draft action plan

FDA has developed this draft action plan to outline its actions and goals on the acrylamide issue. FDA is presenting this draft action plan for input and comments from the public, academia, industry, and scientific experts.

Testing foods

FDA is currently testing a limited number of locally collected foods in its laboratories at the Center for Food Safety and Applied Nutrition (CFSAN). In FY03, FDA also plans to test a larger number of samples collected nationwide by FDA's Office of Regulatory Affairs for analysis by CFSAN and possibly other government and non-government laboratories. The local and national samples will be used to estimate variation within and across key food types as part of processing evaluations and to determine the incidence of formation across the food supply. For FY03, FDA also plans to collect and analyze Total Diet Study (TDS) market basket samples to identify exposures from specific U.S. foods. Further testing may occur in FY03 based on the findings of the initial survey and formation research.

3. Toxicology

Development of new data on toxicology will provide more information about acrylamide and facilitate risk management choices. FDA is initiating and participating in research on a variety of toxicology related issues.

- ♦ FDA's National Center for Toxicological Research (NCTR) is proposing to conduct the following short-term studies:
- ♦ Compare and contrast the bioavailability of acrylamide in both mice and rats when dosed via drinking water and in the diet. These studies should clarify how acrylamide is absorbed in a food matrix and shed light on the significance of previous toxicology assays in

which rats were administered acrylamide in drinking water.

- ♦ Identify acrylamide-related DNA and protein adducts and study the formation of these adducts in mice and rats exposed to acrylamide. Acrylamide-related adducts are reaction products between acrylamide and its metabolites and DNA and proteins.
- ♦ Correlate adduct data from rats with adduct measurements in humans whose only known exposure to acrylamide is through background levels in food or through smoking.
- ♦ FDA NCTR plans to nominate acrylamide and its reactive metabolite glycidamide to the National Toxicology Program as FDA's high priority chemical selections for fiscal year 2003. FDA will request that subchronic toxicity studies, chronic carcinogenicity studies, and supportive mechanistic studies be conducted for both acrylamide and glycidamide. NCTR would conduct these studies through an interagency agreement between FDA and National Institute of Health's (NIH) National Institute for Environmental Health Sciences (NIEHS). FDA will therefore participate in all experimental protocol designs to assure regulatory needs are met.

- ♦ FDA will work with the Centers for Disease Control (CDC) to evaluate the use of acrylamide-related protein adducts for monitoring acrylamide exposures in humans. FDA and CDC will discuss the possibility of including monitoring acrylamide adducts in the National Health and Nutrition Examination Survey (NHANES), a national health survey that collects biological samples and health data from people throughout the U.S.

4. Research and outreach on formation

- ♦ FDA will investigate mechanisms of acrylamide formation and processes for reducing formation of acrylamide through the National Center for Food Safety and Technology (NCFST) in Illinois, a consortium between FDA, the Illinois Institute of Technology, and food-related industries.
- ♦ Through its collaboration with industry, FDA will encourage industry to adopt processes that are successful at reducing acrylamide.
- ♦ FDA will develop educational material to inform consumers about recommended changes in cooking

Continued on next page...

ACRYLAMIDE-- Continued from page 20...

methods to reduce acrylamide, taking into account the need to balance other potential risk factors for consumers, such as the risk of microbial contamination with reductions in cooking time.

- ♦ FDA will continue to interact with academia and industry to encourage research on mechanisms of acrylamide formation and effects of process changes on acrylamide levels. FDA is fostering such interactions through NCFST and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a consortium between FDA and the University of Maryland.

5. Methodologies

- ♦ FDA will continue to update and validate its current liquid chromatography/tandem mass spectrometry (LC/MS/MS) methodology as needed. FDA developed its own LC/MS/MS methodology for testing for acrylamide in foods and posted this methodology on the CFSAN website on June 20, 2002. The methodology was updated on July 23, 2002.

- ♦ Researchers at CFSAN will evaluate screening methodologies for more rapid and less expensive detection of acrylamide in the food supply.

6. Meetings and collaborative projects

FDA is planning to convene or participate in multiple meetings with the goals of (a) gathering public and expert input on acrylamide in food and (b) fostering coordination of research efforts on acrylamide.

- ♦ CFSAN is conducting an interagency roundtable of federal public health agencies involved in acrylamide research on September 24, 2002. Participants in the roundtable include Department of Health and Human Services (FDA, the National Institute of Environmental Health Sciences, and the National Institute of Occupational Safety and Health and the National Center for Environmental Health of CDC), the United States Department of Agriculture (Food Safety Inspection Service, Agricultural Research Service), and the Environmental Protection Agency (EPA). Topics include the results of the WHO consultation, plans for acrylamide toxicology studies at each agency, EPA's reevaluation of its dose-response evaluation for acrylamide, the potential use of biomarkers to monitor acrylamide exposure, epidemiological studies, occupational exposures, and heritable mutagen assays. FDA will continue to chair this inter-

agency group to review ongoing developments relating to acrylamide.

- ♦ FDA is convening a Public Meeting, "Assessing Acrylamide in the U.S. Food Supply," on September 30, 2002, to update the public on FDA's activities related to acrylamide in food, to present FDA's draft action plan for acrylamide, and to obtain comments on the plan.

- ♦ FDA will hold a meeting of the Subcommittee on Contaminants and Natural Toxicants of the FDA Food Advisory Committee in early December 2002. At the meeting, FDA will present its draft action plan for acrylamide, revised to reflect comment from the September 30, 2002, public meeting, and will also present preliminary data on acrylamide levels in foods. FDA will seek input on the draft action plan, on research and analysis needs, and on exposure and toxicology issues.

- ♦ FDA will hold a meeting of the full FDA Food Advisory Committee in late February or early March 2003. FDA will present its revised draft action plan, updated to reflect input from the Subcommittee on Contaminants and Natural Toxicants, as well as preliminary data on acrylamide levels in foods and more specific information on ongoing or planned research. FDA will seek input on the draft action plan, on research and analysis needs, and on exposure and toxicology issues.

- ♦ The Codex Committee on Food Additives and Contaminants meets March 17-21, 2003. The U.S. delegation will work with other delegations to ensure that acrylamide is assessed.

- ♦ If invited, FDA scientists will participate in an assessment of acrylamide by the WHO/FAO Joint Expert Committee on Food Additives and Contaminants (JECFA), tentatively planned for winter or spring 2004.

- ♦ JIFSAN will serve as a clearinghouse for continued international coordination and data sharing on acrylamide.

7. Consumer messages

- ♦ FDA will develop and revise consumer messages about dietary choices and cooking methods, as additional knowledge is gained about acrylamide in food.

Continued on page 22...

ACRYLAMIDE -- from page 21...

8. Regulatory options

♦ FDA will develop and revise regulatory options as additional knowledge is gained on acrylamide in food. Many of the items in the draft action plan are geared toward achieving that end.

The following table highlights the timeline of activities on acrylamide.

Dates*	Activities
September 24, 2002	CFSAN-led interagency roundtable of federal public health agencies on acrylamide research.
September 30, 2002	“Assessing Acrylamide in the U.S. Food Supply”: A public meeting on acrylamide in food.
October 28-30, 2002	JIFSAN/NCFST Workshop, “Acrylamide in Food: What do we need to know? What are the responses?”
Early December 2002	Meeting of the Subcommittee on Contaminants and Natural Toxicants of the FDA Food Advisory Committee.
February or March 2003	Meeting of the full FDA Food Advisory Committee.
March 17-21, 2003	Codex Committee on Food Additives and Contaminants meeting.
Winter-Spring 2004	WHO/FAO JECFA acrylamide assessment (tentative).
Ongoing or planned	National food survey of acrylamide levels in food (including Total Diet Study samples)
	Toxicology studies
	Methodology studies

*Where applicable. Some dates are tentative.

CRAWFORD -- from page 13 ...

received over 14,000 comments, the vast majority opposing the proposed rule.

General Accounting Office (GAO) Study - May 1998 —

In May 1998, the House Committee on Science requested that the GAO examine the scientific basis for the ephedrine alkaloids proposal. On August 4, 1999, GAO released its report entitled: “Dietary Supplements: Uncertainties in Analyses Underlying

FDA’s Proposed Rule on Ephedrine Alkaloids.” The GAO concluded that the Agency needed additional evidence to support these restrictions, recommending FDA “provide stronger evidence on the relationship between the intake of dietary supplements containing ephedrine alkaloids and the occurrence of adverse reactions that support the proposed dosing level and duration of use limits.”

Partial Withdrawal of Proposed Rule & Review of Adverse Events - April 3, 2000 —

On April 3, 2000, FDA withdrew the portions of the ephedrine alkaloids proposed rule relating to the dosing level and duration of use limits for these products. It retained the proposed warning statement and prohibition on including other stimulant ingredients in dietary supplements containing ephedrine alkaloids.

HHS Public Meeting - August 2000 —

The Department of HHS Office of Women’s Health (OWH) held a public meeting on ephedra in August 2000. FDA and two of its outside experts presented their reviews of the 160 AERs referenced above. Industry representatives and their scientific experts also made presentations, as did some consumers and others. In September 2000, OWH issued its report on ephedrine alkaloid dietary supplements (EADS) from the public meeting. They concluded: 1) “Despite the established limitations of AERs, many of the adverse effects are biologically plausible based on the known pharmacologic effects of ephedrine alkaloids. The pharmacology of ephedrine is supported by a rich database, in contrast to the paucity of evidence on the benefits or risks of EADS in humans. The level of concern for continued use of EADS must be based on the totality of information available on ephedra and ephedrine alkaloids, including the AERs, results of human and animal studies, as well as what is known about the pharmacology and chemistry of these compounds. 2) Given the current widespread use of EADS, a consumer education campaign about these products is warranted. Good manufacturing standards are needed, reasonable dose and duration levels determined, and warnings and contraindications clearly indicated on labels. A research agenda should be established. Therefore, the research community should take the next logical step by conducting a systematic review of the world’s literature on ephedra. After compiling the state of the science and identifying the limitations and gaps of the current research, an appropriate agenda can be established. In this regard, the National Center for Complementary and Alternative Medicine of the National Institutes of Health already is requesting proposals to study herb-drug interactions.”

New England Journal of Medicine - November 2000 —

In November 2000, the New England Journal of Medicine published an advance Internet copy of a review of 140 ephedra AERs by Drs. Christine Haller and Neil Benowitz. The results of the study showed that 31% of the cases were considered to be definitely or probably related to the use of supplements containing ephedra alkaloids and 31% were deemed to be possibly related. The article concluded: “the use of dietary supplements that contain ephedra alkaloids may pose a health risk to some persons. These findings indicate the need for a better understanding of individual susceptibility to the adverse effects of such dietary supplements.” The article was based upon an expert review of some adverse events that FDA had provided Dr. Benowitz, as an FDA

CRAWFORD -- Continued from page 22...
consultant.

Department of HHS's Office of Inspector General (OIG) - February 12, 2001 — On February 12, 2001, the OIG published another report: "Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve." They made four recommendations: 1) Facilitate greater detection of adverse events by requiring manufacturers to report to FDA and to conduct greater outreach to health professionals and consumers; 2) Obtain more information on adverse event reports to generate stronger signals by establishing manufacturer and product registries and developing a new computer data base; 3) Obtain more information to assess signals by exploring the possibility of a monograph system, expedite the development of good manufacturing practices and assist the industry in standardizing ingredients; and 4) Disclose more useful information to the public. The recommendation to require adverse event reporting for dietary supplements requires a change in the current law. Also, the recently enacted Bioterrorism law requires both conventional food and dietary supplement manufacturers to register with FDA. FDA is currently drafting proposed regulations to implement this requirement.

Public Citizen Petition - September 5, 2001 — On September 5, 2001, Public Citizen and Dr. Ray Woolsey petitioned HHS to ban the production and sale of dietary supplements containing ephedrine alkaloids on the basis that these products present "a significant or unreasonable risk of illness or injury." On January 31, 2002, Public Citizen petitioned HHS once again to ban products containing ephedra.

Mayo Clinic Proceedings - January 2002 — The January 2002 *Mayo Clinic Proceedings* published an article "Adverse Cardiovascular Events Temporally Associated With Ma Huang, an Herbal Source of Ephedrine." They analyzed 37 patients and found: (1) ma huang use is temporally related to stroke, myocardial infarction, and sudden death, (2) underlying heart or vascular disease is not a prerequisite for ma huang-related adverse events, and (3) the cardiovascular toxic effects associated with ma huang were not limited to massive doses. They concluded that observational and circumstantial evidence indicates that use of the substance may be associated with serious medical complications.

Boozer Daly Study - February 2002 — Drs. Boozer and Daly conducted a study on the utility, safety of a combination herbal preparation consisting of ephedrine alkaloids and caffeine in weight loss. This was accepted for publication in the *International Journal of Obesity (IJO)*, February 2002, (volume 26, page 593-604). It was a six-month placebo controlled trial with a total of 167 subjects. The authors concluded that the preparation promoted body weight reduction without significant adverse events in this study. The Department of HHS and FDA have discussed this study with Drs. Boozer and Daly on two occasions. We are seeking permission to receive raw data from this study, if needed, during our ongoing review. Also, there were two editorials that accompanied this article in IJO that cautioned about the selectivity of study participants.

RAND Study — June 14, 2002 — HHS recently funded the RAND Corporation to conduct a comprehensive review of the existing science on ephedrine alkaloids, particularly those in dietary

supplements. The completion of the review is targeted for the early next year. This scientific review will help guide the Department and the Agency in developing future FDA regulatory actions on ephedrine alkaloids. On a separate track, but at the same time, RAND has also been asked to conduct a dedicated review of a large number of documents from Metabolife. These include 13,000 consumer complaints and an additional 1,700 complaints with approximately 50 medical records. The completion for this review is targeted for later this year.

Metabolife Investigation - July 2002 — In July 2002, FDA asked the Department of Justice (DOJ) to pursue a criminal investigation of Metabolife, to see if they had made false statements to FDA regarding the existence of adverse event reports. That investigation is ongoing at this time.

KEY FOR FDA - THE USE OF SOUND SCIENCE AND THE ABILITY TO OBTAIN NEEDED DATA

CFSAN Adverse Event Reporting System (CAERS) — Adverse events are the primary means FDA has for identifying potential safety problems with dietary supplements. Under DSHEA, FDA must rely on adverse event reports as a major component (i.e.-signal generator) of its post-market regulatory surveillance under DSHEA. Given that most experts estimate that adverse events actually reported to FDA range between 1% to 10% of actual occurrences, much time and resources have been devoted to making this system as effective as possible.

CAERS is a comprehensive computerized system that is being designed to capture and analyze all reports of consumer complaints and adverse events related to CFSAN-regulated products. This system will create a state-of-the-art reporting and monitoring system that will serve as a post-marketing surveillance tool. Also, CAERS can provide a strong signal that is a guide toward further review of relevant scientific information. In conjunction with the design and development of CAERS, CFSAN has developed and is currently staffing a new organizational unit within the Office of Scientific Analysis and Support. This CAERS Staff will serve as the core functional unit for daily operations and will work in conjunction with contractors and Program Offices to ensure a consistent and efficient workflow.

PARTNERING WITH THE FEDERAL TRADE COMMISSION (FTC) - 1997

"Operation Cure.All" — FDA also has enhanced its cooperation with FTC, through "Operation Cure.All" and other efforts. In 1997, FTC, FDA, Health Canada, and various State Attorneys General organized and implemented an ongoing and comprehensive law enforcement and consumer education campaign against the fraudulent marketing of supplements and other health products on the Internet. The agencies have moved to stop Internet scams for supplements and other products that purport to cure cancer, HIV/AIDS, and countless other life-threatening diseases. Since its inception, "Operation Cure.All" has resulted in hundreds of advisory letters directed at sites selling products with egregious claims as well as many enforcement actions directed against the marketing of fraudulent products.

CRAWFORD -- Continued on page 24...

CRAWFORD -- *Continued from page 23...*

The Agency has engaged in several consumer education efforts with FTC including a "Miracle Health Claims: Add a Dose of Skepticism" health fraud brochure. The brochure helps the consumer spot false and unsubstantiated claims and has suggestions on how to avoid being the target of health fraud.

Other Internet Activities - 1996-2002 — In January and February 2002, FDA and FTC participated in an International Internet search, led by the Australian Competition and Consumer Commission and with participation by 19 members of the International Marketing Supervision Network (IMSN), an organization made up of consumer protection agencies worldwide. As a result of the surf, FTC has sent over 280 advisory letters to domestic and foreign sites that were identified as making questionable claims for health-related products or services, dietary supplements. FDA is also making initial contact with Internet sites and alerting them to potential legal problems. The websites FDA visited promote dietary supplement products for treatment of diseases, including arthritis, cancer, and HIV/AIDS. CFSAN will be revisiting these sites to verify whether the website operators made corrective actions. FDA and FTC are evaluating the responses to these advisory letters and they will coordinate appropriate enforcement actions if they are necessary.

ENFORCEMENT ACTION - July 2000 — When a problem arises with a product regulated by FDA, the Agency can take a number of actions to protect the public health. For dietary supplements, as with other products, the Agency initially works with the marketer of the product to correct the problem voluntarily. If that fails, the Agency also can ask the marketer to recall a product, although it cannot order a recall. The Agency can also seek, through the courts, seizure of violative products and/or an injunction against firms or individuals who market violative products, and detain or refuse entry of products presented for import at U.S. ports. FDA has taken several enforcement actions pertaining to ephedra or ephedrine alkaloids. In most cases, FDA took action against these products because they contained drug ingredients, because they were promoted to treat a disease, and/or because they presented safety concerns. In fiscal year 2002, Congress appropriated \$500,000 for dietary supplement enforcement efforts.

Nature's Nutrition Formula One - July 2000 — FDA determined that this pre-DSHEA product, which was marketed between 1992 and 1994, as an all natural "nutritional supplement" that contained plant ingredients, was actually made with two pharmaceutical-grade chemicals, ephedrine hydrochloride and caffeine anhydrous. FDA received more than 100 reports of injuries and adverse reactions related to the product, ranging from serious and life-threatening conditions, such as irregular heartbeat, heart attack, stroke, seizures, hepatitis and psychosis, to more minor and temporary conditions such as dizziness, headache and gastrointestinal distress. At least one death was associated with the use of this product.

This case was developed by the alerts provided from the adverse event reports, by Office of Regulatory Affairs field staff, and by the work of FDA's Office of Criminal Investigation with the Department of Justice. As a result, the government launched a criminal prosecution against the company and its president.

On July 7, 2000, a Federal judge sentenced the president of Chemins to 21 months in jail and fined him and his corporation \$4.7 million. The sentence marked the culmination of a three-year investigation.

E'OLA International, Inc. - April 2002 — At the request of FDA, U.S. Marshals seized unapproved drug products from Biogenics Inc., of St. George, Utah, doing business as E'OLA International, and at its contract manufacturer, Nature's Energy, Inc., of Pleasant Grove, Utah. About 140,000 bottles of AMP II Pro Drops valued at \$2.8 million were seized, along with the bulk ephedrine hydrochloride (HCl) used in its manufacture. Although the finished products contained a drug, ephedrine HCl, they were labeled as dietary supplements for use in weight loss. The products, however, do not meet the definition of a dietary supplement because ephedrine HCl is not a dietary ingredient under the Act. In April 2002, a United States District Court Judge signed a Consent Decree of Permanent Injunction that prohibited E'OLA from holding, manufacturing, processing, packing, labeling, promoting, or distributing AMP II Pro Drops or any similar product containing or purporting to contain ephedrine HCl or any synthetic ephedrine alkaloid. Under the decree, E'OLA was also required to destroy the seized articles at its own expense under the supervision of an HHS representative.

Additional FDA Actions — FDA is still awaiting the scientific review from the RAND study, so we can better understand the safety and efficacy of ephedrine alkaloids. In the meantime, FDA is taking the following steps:

Good Manufacturing Practices (GMPs) - October 2002 — There is broad public support for dietary supplements GMPs to enhance public confidence in these products. On Friday, October 4, 2002, the proposed rule was forwarded to Office of Management and Budget for a 90-day review.

Aggressive Enforcement of Synthetic Products — In addition to our prior efforts on synthetic ephedrine alkaloid enforcement, FDA is interested in conducting a systematic pharmacological analysis of ephedra products on the market to assess the need for further enforcement against products that contain synthetic ephedrine alkaloids.

Increased Enforcement of Illegal Ephedrine - June 14, 2002 — FDA is aggressively pursuing the illegal marketing of non-herbal synthetic ephedrine alkaloid products and sent six warning letters to firms unlawfully selling non-herbal ephedrine alkaloid-containing products over the Internet. These products violate the law because they are not legal dietary supplements and are illegal drugs. Also, FDA warned another company for illegally promoting its herbal ephedra product as an alternative to street drugs.

Warning Labels — Secretary Thompson has requested that FDA evaluate mandatory warning labels as quickly as possible to properly alert the public regarding potential risks associated with the consumption of dietary supplements containing ephedrine alkaloids.

Yellow Jackets — FDA issued a Cyber letter to the foreign distributor of "Yellow Jackets" and alerted consumers that these products present health risks. It is working closely with law enforcement officials in the Netherlands and the U.S. Customs Service to block entry of Yellow Jackets into this country by placing this

FTC ISSUES REPORT ON NUTRITION AND HEALTH CLAIMS IN ADVERTISING

The Federal Trade Commission's Bureau of Economics on October 31, 2002 released a staff report titled Advertising Nutrition & Health, Evidence from Food Advertising 1977-1997 by economists Pauline M. Ippolito and Janis K. Pappalardo. The report reviews data collected by Commission staff on the types of claims made in 11,647 advertisements taken from a sample of eight leading magazines between 1977 and 1997. The primary focus of the study is on advertising claims related to health and nutrition, but it also examines other types of advertising claims. The report further reviews how nutrition-related claims in advertising changed under the various regulatory policies in place during these years.

The FTC staff found that nutrition-related claims were a major focus of food advertising and an important focus of competition during the two-decade period covered by the report. Moreover, data indicate a sustained movement toward specific nutrient claims, such as "low fat," in place of, or in addition, to more general nutrition claims, such as "nutritious." And the study finds that changes in advertising content appear to be associated with changes in regulatory rules and enforcement policies.

The study documents an increased focus on diet and health issues in advertising in the late 1980s and changes in the use of health claims before and after the passage of the Nutrition, Labeling and Education Act of 1990 (NLEA). For instance, at their peak in 1989, heart disease and serum cholesterol claims were made in 8.2 percent of advertisements, before dropping substantially in the early 1990s following the NLEA's passage. By 1997 heart disease and serum cholesterol claims had again risen somewhat and were found in 3.4 percent of ads, 41 percent of the peak level.

In the post-NLEA period, the report also found a substantial narrowing of the nutrition focus in advertising. For nutrient content claims, total fat had become the primary focus of advertising competition by 1997, replacing claims for other major risk factors such as saturated fat, cholesterol, and sodium. Additionally, comparative claims had dropped to very low levels for all nutrients except total fat. Data indicate that competition on major nutrients peaked in 1991. By 1997, the average number of nutri-

ents in ads with nutrient claims returned to the level of the mid-1980s, a 33 percent drop from the peak.

For health claims, the most dramatic change after the NLEA occurred in the market for fats and oils, where claims about the health reasons to choose one fat over another have been eliminated in advertising. Advertising for fruit and vegetables also fell 50 percent after the NLEA, but orange juice producers who continued to advertise were more likely to use health claims.

The report provides a wealth of detailed information on the content of food advertising under the different policies adopted during the years 1977-1997. Together with other research on consumer food choices under the different policies, it should contribute to more informed policy choices on advertising and labeling policy.

The views expressed in the study are those of the authors and do not necessarily represent the view of the Federal Trade Commission or any individual Commissioner. The complete 30-plus page report is available on the FTC website at www.ftc.gov.

NEW DRIs AND THE TRANS FAT FIGHT

Earlier this fall the Institute of Medicine's Food and Nutrition Board (FNB) reported some new recommended Dietary Reference Intakes (DRIs) for healthy eating and it also recommended that individuals have an hour of exercise every day. To meet the body's daily energy and nutritional needs while minimizing risk for chronic disease, adults should get 45 percent to 65 percent of their calories from carbohydrates, 20 percent to 35 percent from fat, and 10 percent to 35 percent from protein, says the newest report on recommendations for healthy eating from the National Academies' Institute of Medicine. To maintain cardiovascular health at a maximal level, regardless of weight, adults and children also should spend a total of at least one hour each day in moderately intense physical activity, which is double the daily minimum goal set by the 1996 Surgeon General's report.

You can get all the details from the website of the Institute of Medicine at <http://www4.nas.edu/news/isbn/0309085373?OpenDocument>.

See TRANS FAT -- on page 26...

USP SEEKS COMMENT ON REVISIONS FOR 14 MONOGRAPHS

On October 31, 2002, the United States Pharmacopeia (USP) announced it is seeking final public comment on revisions made to 14 dietary supplement monographs. These revised monographs are scheduled to be official in the second Supplement of the United States Pharmacopeia 26 and National Formulary 21 (USP 26-NF 21). The monographs appear in the In-Process Revision section of the PF. This is an opportunity to provide comments before the monographs are published in the USP-NF.

These are published in *Pharmaceutical Forum* USP's journal of standards development and the primary vehicle for the public to provide input or comments on USP standards. For the following monographs USP is seeking public comment on:

- Botanical Monographs
- Black Cohosh
- Powdered Black Cohosh
- Powdered Black Cohosh Extract
- Black Cohosh Tablets
- Nutritional Supplement Monographs
- Aspartic Acid
- Calcium Carbonate
- Mineral Capsules
- Mineral Tablets
- Oil- and Water-Soluble Vitamins Tablets
- Oil- and Water-Soluble Vitamins with Minerals Capsules
- Oil- and Water-Soluble Vitamins with Mineral Tablets
- Oil-Soluble Vitamins Tablets
- Water-Soluble Vitamins with Minerals Capsules
- Water-Soluble Vitamins with Minerals Tablets

Comments on the proposed dietary supplement monographs should be addressed and mailed by Feb. 17, 2003 to Dr. Gabriel Giancaspro at USP, 12601 Twinbrook Parkway, Rockville, MD 20852. Additional questions concerning dietary supplement monographs can be sent to mediarealtions@usp.org.

TRANS FAT -- Continued from page 25...

These DRIs are not law, but they could become part of regulations if adopted by other agencies, like FDA. So *NML* readers, like power bar makers, ought to be-

come acquainted with the basics as well as differing views on the new recommendations.

FDA's Docket 94P-0036 contains some of the developing story about the issue of *trans* fat that may be one of the most important issues now pending in the Petition by the Center for Science in the Public Interest (CPSI). CPSI wrote FDA on August 14, 2002, to urge FDA to adopt the agency's initial proposal to include *trans* fat in the percent daily value %DV for saturated fat. CPSI says that the IOM's FNB recommendations supports FDA's 1999 conclusion. CPSI said it had done a survey of 600 consumers. 81% said that food labels should list *trans* fat in addition to saturated fat. CPSI said that when asked whether 4 grams of *trans* fat per serving was small, moderate, or large, 70 percent said they did not know. Only 15 percent answered correctly that 4 grams is a large amount, with 7 percent answering "small" and 8 percent saying "moderate." Therefore, CPSI says that *trans* fat information must be presented in a way that enables consumers to understand the significance in the total diet. And 79 percent said that the label should indicate the percentage of a maximum daily intake of *trans* fat a serving of that food supplies.

CPSI wants the FDA to use the Canadian approach of displaying the amounts of saturated fat and *trans* fat separately, but including both in one %DV. At least this should be an alternative. See letter of August 14, 2002 in Docket 94P-0036, control number 02 4267.

Where do Americans get *trans* fat? Mary G. Enig, Ph.D. cited the July 5 *Time Magazine's* Health section saying that Americans that could have benefited from some accurate data on the amounts of *trans* in foods. She pointed out the *Time* writer has written that "...fried fast foods like French fries...account for up to 75% of the trans-fatty-acids consumed...in the U.S. each year"; but although French fries are a major source of *trans* in many diets, they vie for being the major source in other diets with all of the breads, crackers, cookies, cakes, pastries, and other processed foods. In fact, the margarines supply about 20-25% and the rest is supplied by many fried and baked products. You can learn more about Dr. Enig's reports at www.enig.com.

Three faculty members of the Harvard School of Public Health – Meir Stampfer, Frank Sacks, and Walter Willet, all medical doctors as well, have commented on

Continued next page...

TRANS FAT -- Continued from page 26...

the matter of FDA requiring that the amount of *trans* fat to be included in the amount and %DV for saturated fat. These experts say that it is not optimal to lump these together because it obscures the difference in the adverse effect. *Trans* fat is about twice as bad, gram for gram, in having an adverse effect on the total-to-HDL ratio, because saturated fat, while raising LDL, also raises HDL. In contrast, *trans* fat raises LDL, but lowers HDL. The data shows that consumers should eat as little as possible of *trans* fat and attempt to eliminate it from the diet.

They said the alternative line of reasoning holds that olive oil would be labeled with a larger saturated-plus-*trans* content (though it has no *trans*) than some baked goods whose fat is mostly hydrogenated vegetable oil. The three professors say that alternative makes no sense. See Docket. No. 98N-0044, August 21, 2002, Control No. 02 4270.

CPSI also sent in a letter of August 7, 2002 signed by 33 interested scientists giving similar arguments for the Canadian labeling plan which clusters *trans* fat with saturated fat in Nutrition Facts labels and use a combined Daily Value. Docket No. 94P-0036/98N-0044, FDA Control No. 02 4162.

This is one of hundreds of scientific controversies that FDA has been looking at for years and years.

USP ANNOUNCES WEIDER JOINS DSVP

In early October, the USP announced that it had signed up Weider Nutrition International for its Schiff brand of Move Free products. The Dietary Supplement Verification Program (DSVP) responds to a need to inform consumers that the products contain the ingredients stated on the label.

Bruce Wood, chief executive officer of Weider, said, "Quality is one of the defining attributes of the Schiff brand. As the flagship product of the Schiff supplement line, Move Free is already widely known and trusted by consumers. Our participation in the USP DSVP program is intended to further develop this trust. We are looking forward to submitting other Schiff vitamin/mineral/supplement products for DSVP certification in the future." The

Move Free brand will carry the certification mark by January 2003.

The DSVP program was launched in November 2001 to safeguard consumers who use dietary supplements. If products meet USP's rigorous standards, they will be permitted to use the program certification mark. That mark will help assure everyone that the product contains the declared ingredients on the product label, contains the amount or strength of ingredients declared on the label, meets requirements for limits on potential contaminants, and has been manufactured properly by complying with USP and proposed FDA standards for "good manufacturing practices."

More information can be obtained from the USP at www.USP.org.

NNFA PLANS GMP PROGRAM

With the FDA testimony that it had submitted the proposed Good Manufacturing Practices (GMP) regulations to the Office of Management and Budget (OMB) in October, the National Nutritional Foods Association (NNFA) has announced a program to cover the details. Titled "FDA Dietary Supplement GMPs: What you Need to Know," registrations are being taken for this webcast program to be presented at some future date.

The OMB gets 90 days to review the regulations and could approve, change or send them back to FDA. The agency has been saying for years that it was waiting on other events to happen before the regulations would issue, but NNFA seems to think that the magic time has arrived only eight years after the DSHEA amendments were enacted.

Scott Bass, Esq., an attorney with Sidley Austin Brown & Wood, in Washington, D.C. and Carl Reynolds, of AAC Consulting, formerly of FDA for 36 years, will be the main panelists. Phillip Harvey, Ph.D., NNFA's Director of Science and Quality Assurance and Chief Science Officer will moderate.

NNFA says registration now saves \$50 for the two hour program. The early fee is \$129 for members of NNFA, and \$229 for non-members. Forms are available on the website at www.nffa.org, but there did not

Continued on page 28...

seem to be online registration. Instead, NNFA wants the forms downloaded, and mailed or faxed. The fax number for credit card registration is (94) 622-6266. Or you can get the form, and mail it to: NNFA, Dept. #7913, Los Angeles, CA 90084-7913. Or if you want to speak to someone call, (800) 966-6632.

INTERESTING RESEARCH

Three researchers report that **duct tape** is better than cryotherapy for common warts. The cryotherapy (liquid nitrogen) was applied to each wart for 10 seconds every 2-3 weeks. The duct tape was applied directly to the wart for 2 months. 26 patients treated with duct tape had 85% (22 patients) resolution of the warts. But only 60% (15 patients) of the cryotherapy treated 25 patients had complete resolution of warts. Dean R. Focht, III, MD, Carole Spicer, RN, Mary P. Fairchok, MD, *Arch Pediatr Adolesc Med*, 2002; 156:

971-974

Glucosamine Sulfate delays progression of knee osteoarthritis of mild to moderate severity in a study of 202 patients over three years. At the beginning the patients had an average joint space widths of slightly less than 4 mm and a Lequesne Index score of less than 9 points. At the end, the placebo group was -0.19 (95% confidence interval, -0.29 to 0.09 mm) after three years. Conversely, with glucosamine sulfate use (0.04 mm; 95% confidence interval, -0.06 to 0.14 mm) after three years. Symptoms improved as much as 20 to 25% with glucosamine sulfate. Karel Pavelka, MD, PhD; Jindriska Gatterova, MD; Marta Olejarova, MD; Stanislav Machacek, MD; Giampaola Giacobelli, PhD; Lucio C. Rovati, MD, *Arch Int Med*. 2002; 162: 2113-2123.

Co-Q10 slows functional decline in Parkinson's disease. See the Oct. 14 release from the National Institute of Neurological Disorders and Stroke. www.ninds.nih.gov/.

HARVESTING HEALTH

There is no shortage of legislation, regulations, issues, and research on dietary supplements, just too few hours to keep up. So *NML* added four more pages this issue to help you keep up with more.

Citizen Petitions are taking their toll at FDA. One petition filed December 5, 2000 was turned down by an FDA letter of September 27, 2002. This one was filed by the Center for Science in the Public Interest, affectionately known by some as the "food police." CSPI asked FDA to take action against garlic supplements as

their labeling allegedly contains unauthorized health claims and/or false and misleading structure function claims linking the ingestion of garlic to cholesterol levels, heart disease, and cardiovascular health.

FDA explained that Citizen Petitions are an avenue to ask FDA to take administrative actions, such as initiating a proceeding to issue, amend, revoke a regulation or order. It is not a vehicle to seek enforcement actions. (See 21 CFR 10.3(a)). FDA denied the petition after almost two years.

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Good for FDA. The agency finally realizes it cannot do everything that everyone asks it to do.

But FDA added in its denial of the Citizens Petition that it would review the information in the petition about particular products and claims. FDA said "we will consider whether a violation of the [FFDCA] has occurred, and, if so, whether regulatory action is warranted in light of FDA's enforcement priorities and resources."

FDA should say this more often.

*William J. Skinner, R.Ph.,
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