

# Natural Medicine Law™ Newsletter

## FTC CHARGES MARKETERS OF EPHEDRA WEIGHT LOSS PRODUCTS

The Federal Trade Commission on July 1, 2003 announced three enforcement actions against direct marketers of weight-loss products containing ephedra. The two settlements and one complaint, filed in U.S. district court, target deceptive efficacy, safety, and “no side effects” claims for weight loss supplements containing ephedra (also known as Ma Huang). The FTC actions challenge false advertising claims that the ephedra supplements cause rapid, substantial, and permanent weight-loss without diet or exercise, and that “clinical studies” or “medical research” prove these claims. The FTC also challenges claims that the ephedra weight-loss products are “100% safe,” “perfectly safe,” or have “no side effects.”

The FTC previously brought four enforcement actions challenging deceptive safety and “no side effects” claims for ephedra supplements marketed for body-building and energy, and as alternatives to street drugs like Ecstasy.

“In these cases, the marketers both overstated the benefits and understated the risks of using the products,” said Howard Beales, Director of the FTC’s Bureau of Consumer Protection. “With these enforcement actions, we’re putting the marketers of ephedra supplements on notice that the law demands substantiation for your advertising claims, and the FTC will do its best to make sure you have it.”

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## PRESIDENT BUSH ASKS USDA AND HHS TO UPDATE PYRAMID

Using the “Prompt Letter” approach for the second time on a food issue on May 27, 2003, President Bush asked the two agencies to update their advice to Americans about what food to eat. The first letter, on September 18, 2001, was overshadowed by the events of September 11, but at that time President Bush’s Office of Management and Budget asked HHS to do something about labeling *trans* fat in food products. Secretary Thompson promised a reply by mid-December. Persons following the issue know that FDA is still compiling a file on the subject.

The May 27, 2003 letter pushes the subject of food and diets again, acknowledging the obvious research studies that point to ways to do something to improve the health of many Americans. The mission seems clear and the likely results seem even dramatic, but what will the plodding Agencies do?

*NML* quotes the latest letter from OBM Administrator John D. Graham, Ph.D. to USDA and HHS:

“The purpose of this letter is to request that the Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) further incorporate the large body of recent public health evidence linking food consumption patterns to health and disease as the *Dietary Guidelines for Americans* is revised for its scheduled 2005 release and to update the

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## FTC AND FDA TAKE NEW ACTIONS IN FIGHT AGAINST DECEPTIVE MARKETING

The Federal Trade Commission on June 10, 2003 charged the marketers of a dietary supplement called Coral Calcium Supreme with making false and unsubstantiated claims about the product’s health benefits. This action is part of a series of initiatives the FTC and the Food and Drug Administration (FDA) are taking against the purveyors of products with unsubstantiated health and medical claims.

In a complaint filed in federal district court, the FTC alleges that Kevin Trudeau; Robert Barefoot; Shop America (USA), LLC; and Deonna Enterprises, Inc., violated the FTC Act by claiming, falsely and without substantiation, that Coral Calcium Supreme can treat or cure cancer and other diseases, such as multiple scler-

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The FTC also is challenging weight-loss claims for several other non-ephedra dietary supplements. One case challenges safety and efficacy claims for a dietary supplement used to treat impotence in men, and another challenges claims that a glucosamine and chondroitin dietary supplement “cures” arthritis.

The two settlements announced today require Health Laboratories of North America, Inc., USA Pharmacal Sales, Inc., and their principals to stop making false and deceptive advertising claims, to include warnings about the health risks of ephedra and certain other products, and to pay a total of \$370,000 in consumer redress. The third case, against Michael S. Levey and others, will proceed to litigation.

### Michael S. Levey

The FTC charges California residents Michael S. Levey and Gary Ballen; Bentley Myers International Co., based in Vancouver, Canada; and Publisher’s Data Services, Inc. and Nutritional Life, Inc., both based in Beverly Hills, California, with violating the FTC Act in marketing dietary supplements purported to cause rapid and substantial weight loss without diet or exercise and to “cure” arthritis. Levey and Ballen control the companies. In addition, the FTC is charging Levey and the three companies with violating a 1993 FTC order in connection with these marketing activities. The complaint, filed by the Department of Justice on behalf of the FTC, alleges that the defendants:

- made false or unsubstantiated claims that three purported weight loss products – Zymax and MillinexES (both containing ephedra), and

Serotril (containing St. John’s wort) – cause substantial weight loss in a short period of time, without the need to diet or exercise;

- made unsubstantiated “no side effects” claims for the Zymax and MillinexES ephedra products;
- falsely represented that clinical studies prove that Zymax and MillinexES cause substantial weight loss in a short time without diet or exercise; and
- made unsubstantiated claims that CartazymeDS, a dietary supplement containing glucosamine and chondroitin, “cures” arthritis, “rebuilds” cartilage in human joints “within days,” and is an effective alternative to joint replacement surgery.

The complaint alleges that the defendants advertised these weight loss and arthritis products in brochures that used fictitious expert endorsements, fake consumer testimonials, and false “before and after” pictures. The defendants allegedly used different business names in marketing their products, such as “Denman Scientific Research” in ads for Zymax, “Cartazyme Sciences International” in ads for CartazymeDS, and “Serotril Sciences, International” in ads for Serotril.

The complaint also alleges that Levey violated the 1993 order by failing to notify the FTC within 30 days after he became affiliated with Bentley Myers and Publisher’s Data Services. The FTC’s 1993 cease and desist order against Michael Levey and his

company, Positive Response Marketing, Inc., was based on allegations that Levey made false and misleading representations in television infomercials for the EuroTrym Diet Patch, the Foliplexx hair-loss product, and the Y-Bron impotence treatment, and performed deceptive demonstrations in infomercials for the Magic Wand kitchen mixer.

In addition to requiring a \$275,000 redress payment, the order prohibits Levey from making unsubstantiated advertising claims and from using deceptive endorsements and demonstrations, and imposes certain recordkeeping and reporting obligations.

The FTC is seeking monetary civil penalties from Levey and the three companies for violations of the 1993 order, and also is seeking consumer redress and injunctive relief from all the defendants.

The Commission vote to refer the Levey complaint to the Department of Justice for filing was 5-0. The complaint was filed at the FTC’s request by the Department of Justice in U.S. District Court for the Central District of California, on June 30, 2003.

### Health Laboratories of North America

The FTC’s complaint names Health Laboratories of North America, Inc. (HLNA), based in Scottsdale, Arizona, and its director, Marc Kaplan. According to the FTC, the defendants marketed two products under the brand name “Berry Trim Plus” primarily through direct mail. Both products contained Hydroxycitric Acid or “HCA,” an extract from brindall berries, and one also contained ephedrine alkaloids from Ma

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### SECTION 403 LETTERS

More than 10,500 structure/function claims have been filed by manufacturers and distributors for dietary supplement products. The Food and Drugs Administration has reviewed all of these and selected almost 700 to send letters of objection back to the sponsors. These letters of objection advise that the claims are not proper under Section 403(r)(6) for various reasons. Here are summaries of the latest letters from sponsors with FDA's responses in abbreviated form.

**Synergy Worldwide** of Orem, Utah, wrote FDA on February 26, 2003 stating that it would market eleven new products, including one named Young Again, with the claim that *"Young Again features the latest in anti-aging hormone technology, including an exclusive blend of powerful human growth hormone releasers, DHEA, Pregnenolone and natural Progesterone. These hormones are some of the most powerful anti-aging compounds known to man."* FDA's response of April 2, 2003 stated that progesterone was approved as a new drug and was not marketed as a dietary supplement or as a food prior to that new drug approval. Therefore, FDA stated that a dietary supplement may not contain this ingredient. The claims evidence that the product is intended to affect the structure and function of the human body and therefore, under the statutory definition of drug, this product is a new drug requiring a new drug application. Dkt. No. 97S-0163, Ltr. 683.

**Kemin Consumer Care, L.C.** of Des Moines, Iowa, wrote FDA on March 20, 2003 that it would market a product named Satise™ that contains 15 mg of the potato

protease inhibitor PI2 according to the notice. However, the label enclosed stated the ingredient was potato protein extract. The claim for the products was *"Helps produce feeling of fullness to manage hunger naturally."* FDA responded on April 2, 2003 stating that the limited information provided indicates that this extract is a new dietary ingredient, requiring the submissions of information in compliance with 21 USC 350b and 21 CFR 190.6. Since this ingredient has not been present in the food supply, the required 75-day notice must be filed before introducing the product into commerce. The letter was signed by Robert J. Moore, Ph.D., for Susan J. Walker, M.D., and stated FDA's position was that the mere presence of components of your product in food marketed in the United States before October 15, 1994, does not mean that the dietary ingredient is not a new dietary ingredient. FDA believes that it must be shown that potato protein extract qualifies as "an article used for food in a form in which the food has not been chemically altered" under the statute. FDA did not mention the claim itself as being violative. Dkt. No. 97S-0163, Ltr. 684.

**Young Living Essential Oils** of Payson, Utah, wrote FDA on March 12, 2003 stating that it would market Super B, with the following claim: *"Supports a positive outlook and healthy energy levels. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease. As part of a well-balanced diet that is low in saturated fat and cholesterol, folic acid, vitamin B6 and vitamin B12 may reduce the risk of vascular disease. FDA evaluated this claim and found*

*that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of this claim is inconclusive."* FDA responded on April 2, 2003 that the claim is not a Section 403(r)(6) claim, but a claim under 21 USC 403(r)(1)(B) since it implies the product will prevent a disease, i.e., vascular disease. FDA then referred to its November 28, 2000 letter to another sponsor in which the FDA said it would permit an appropriate qualified claim that the agency later on May 15, 2001 affirmed and had modified on February 9, 2001. These letters can be seen on the FDA website at [www.cfsan.fda.gov/~dms/ds-labl.html](http://www.cfsan.fda.gov/~dms/ds-labl.html). A label that is not properly qualified or consistent with the weight of the evidence is subject to regulatory action as a misbranded food under section 403(r)(1)(B), as well as being a misbranded drug under section 502(f)(1), and an unapproved new drug under section 505(a). Dkt. No. 97S-0163, Ltr. 685.

**Confidence USA, Inc.** of Fresh Meadows, New York, wrote to FDA on December 6, 2002 to state that it would make eight separate claims for the product Fe-Mon-9, containing daily doses of Red Clover 100 mg. Black Cohosh 100 mg., Dong Quai Root powder 100 mg., Damiana Leaf powder 100 mg., Gamma Oryzanol 100 mg., L-Arginine 100 mg., L-Lysine 100 mg, DHEA 10 mg, and Pregeneolone 10mg. The letter from

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## GMP COMMENTS TRICKLE

Comments on the dietary supplement GMPs are trickling in to FDA these days, reaching the level of 117 just a week before the June 11, 2003 deadline. In some of the latest comments filed at the Docket Clerk's Office are a page of comments by Rebecca's Natural Food of Charlottesville, Virginia, three and a half page comment by Gaia Herbs of Brevard, North Carolina, and a one-page comment from the Korner Pharmacy in Clinton, Washington.

Susan J. Dunlap, Nutrition Information Specialist, at Rebecca's "applauded" the proposed regulations, but said FDA should rethink them and require manufacturers to: 1) "conduct dissolution and disintegration testing supplements;" 2) conduct stability testing and label products with expiration dates; 3) ensure production performance through the use of written standard procedures; 4) develop, validate and follow cleaning and sanitation procedures; and 5) use these four points as part of a comprehensive quality control program, and not rely on 100% inspection of finished production batches. The letter also pointed out that these points were not covered in the economic analysis and that this dramatically underestimates the costs required to implement the proposal. Dunlap was concerned that the current proposal and economic analysis could have a negative impact on the choices of supplements for customers.

Gaia's May 21 letter is signed by James A. Grant, Compliance Officer, and Greg Cumberford, Senior Resources Manager, asks FDA to clarify the Personnel Sections 111.12 and 111.13 as to what type of training and experience is required. They request guidance on the meaning of

"qualified" personnel. Also, as to physical plants, section 111.20, they request language to explain the requirements.

And under Subpart D pertaining to Equipment and Utensils, section 111.25(3)e concerning the cleaning of wet processing equipment, they point out that "sanitize" is defined as application of heat or chemicals to yield a reduction of 5 logs, equal to 99.999 percent reduction, of representative disease microorganisms of public health significance. They said the proposed language is like the drug GMP language at 21 CFR 211 and the intent of DSHEA was not to have drug GMPs. They believe this misdirects the intent of the law to an overly impractical means, not of achieving sanitized conditions, "but of consistently validating them." They recommended the language be changed to state that equipment, etc. be cleaned and sanitized in a manner that keeps microorganisms and other adulterants from contaminating all components, ingredients, in-process and finished product. The burden of proof of purity should be on the product, rather than on the product contact surfaces, and this they said, "delivers safety to consumers in a feasible and proper manner."

For Production and Process Controls, section 111.35 g(1), they disagree with testing each finished batch since this implies that raw materials and in-process components need only be tested if there is no valid scientific method to test the *finished* product. They recommend the language allow for other strategies if proven better and more scientifically valid. Just testing *finished* products would prevent recovery or reprocessing steps to be made. Instead, testing components prior to blending makes more



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sense, they said. Absence of a valid scientific test for *finished* batch testing should not be the only allowable trigger for sub-component testing.

In section 111.35(1) Gaia officials asked for clarification on whether gross organoleptic analysis alone can be an adequate and valid test methodology for releasing finished products. If so, they propose FDA also say that gross organoleptic analysis *cannot* substitute for microbial and heavy metals analysis. They suggested that TLC, HPLC, GC-MASS, and other tests must be used in conjunction with gross organoleptic analysis to assure the quality, purity, strength, identity, and consistency of every batch of every finished product.

Gaia officials questioned under section 111.50(c)2, whether individual names of production officials must be identified in batch records by name

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## AMENDMENTS TO DIRECTIVE 2001/83/EC

On May 30, 2003, the Commission on European Communities presented amendments concerning herbal medicinal products for discussion. Member states are nominating five persons each for the Committee on Herbal Medicine and the Executive Director will select one person from each state keeping in mind the need for a multidisciplinary Committee. Terms shall be three years. The Committee shall establish contacts with associations of people affected, patients, and people working in the sector for advisory purposes. These and other changes can be reviewed on the web at <http://dg3.eudra.org>.

On June 12, 2003, the General Secretariat reported to the Delegations in 10449/03 that certain amendments and changes were proposed for adoption concerning the procedures for authorization and supervision of medicinal products for human use and veterinary use and for the establishment of a European Agency for the Evaluation of Medicinal Products. At Article 50 of this document the Committee on Herbal Medicinal Products is reaffirmed (page 55 of a 79 page document). Interestingly the Committee on Herbal Medicinal Products is bracketed unlike any other subsection naming a committee. The only other use of brackets in the entire document is to reserve space for future sections. The Regulation becomes effective 20 days after publication in the *Official Journal of the European Communities*.

The EC has been busy with passing amendments to Directive 2001/83/EC during recent weeks. For example, in L 159, Volume 46 of the *Official Journal of the European Communities* for June 27, 2003,

three Commission Regulations were published. These were Commission Regulations (EC) No. 1084/2003 of 3 June 2003, No. 1085/2003 of 3 June 2003, and Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC. These and other amendments make multiple changes in the approval process for the EC. Herbal medicines are mentioned in these amendments.

Of particular interest to *NML* readers is Commission Directive 2003/63/EC of June 25, 2003 that was published in the *Official Journal of the European Communities* on 27 June, 2003. It contains the following statements that pertain to herbal medicine.

4. HERBAL MEDICINAL PRODUCTS  
Applications for herbal medicinal products shall provide a full dossier in which the following specific details shall be included.

### Module 3

The provisions of Module 3, including compliance with monograph(s) of the European Pharmacopoeia, shall apply to the authorisation of herbal medicinal products. The state of scientific knowledge at the time when the application is lodged shall be taken into account.

The following aspects specific to herbal medicinal products shall be considered:

- (1) Herbal substances and herbal preparations

For the purposes of this Annex the terms 'herbal substances and preparations' shall be considered equivalent to the terms 'herbal drugs and herbal drug preparations', as defined in the European Pharmacopoeia.

With respect to the nomenclature of the herbal substance, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal substance, the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided.

With respect to the nomenclature of the herbal preparation, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal preparation, the ratio of the herbal substance to the herbal preparation, the extraction solvent(s), the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided.

To document the section of the structure for herbal substance(s) and herbal preparation(s) where applicable, the physical form, the description of the constituents with known therapeutic activity or markers (molecular formula, relative molecular mass, structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass) as well as other constituent(s) shall be provided.

To document the section on the manufacturer of the herbal substance, the name, address, and responsibility of each supplier, including contractors, and each proposed site or facility involved in production/ collection and testing of the herbal substance shall be provided, where appropriate.

To document the  
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section on the manufacturer of the herbal preparation, the name, address, and responsibility of each manufacturer, including contractors, and each proposed manufacturing site or facility involved in manufacturing and testing of the herbal preparation shall be provided, where appropriate.

With respect to the description of manufacturing process and process controls for the herbal substance, information shall be provided to adequately describe the plant production and plant collection, including the geographical source of the medicinal plant and cultivation, harvesting, drying and storage conditions. 27.6.2003 EN L 159/87 Official Journal of the European Union

With respect to the description of manufacturing process and process controls for the herbal preparation, information shall be provided to adequately describe the manufacturing process of the herbal preparation, including description of the processing, solvents and reagents, purification stages and standardisation. With respect to the manufacturing process development, a brief summary describing the development of the herbal substance(s) and herbal preparation(s) where applicable shall be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the herbal substance(s) and herbal preparation(s) where applicable used in supporting bibliographic data and the herbal substance(s) and herbal preparation(s), where applicable, contained as active substance(s) in the herbal medicinal product applied for shall be discussed, where appropriate.

With respect to the elucidation of the structure and other characteristics of the herbal substance, information on the botanical, macroscopical, microscopical, phyto-chemical characterisation, and biological activity if necessary, shall be provided.

With respect to the elucidation of the structure and other characteristics of the herbal preparation, information on

the phyto- and physicochemical characterisation, and biological activity if necessary, shall be provided.

The specifications for the herbal substance(s) and herbal preparation(s) where applicable shall be provided. The analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided.

With respect to the validation of analytical procedures, analytical validation information, including experimental data for the analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided. With respect to batch analyses, description of batches and results of batch analyses for the herbal substance(s) and herbal preparation(s) where applicable shall be provided, including those for pharmacopoeial substances. Justification for the specifications of the herbal substance(s) and herbal preparation(s) where applicable shall be provided. Information on the reference standards or reference materials used for testing of the herbal substance(s) and herbal preparation(s) where applicable shall be provided. Where the herbal substance or the herbal preparation is the subject of a monograph, the applicant can apply for a certificate of suitability that was granted by the European Directorate for the Quality of Medicines.

#### (2) Herbal Medicinal Products

With respect to the formulation development, a brief summary describing the development of the herbal medicinal product should be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the products used in supporting bibliographic data and the herbal medicinal product applied for shall be discussed, where appropriate.

Companies who want to market herbal products in Europe may soon find that the regulatory thicket has been thinned, but on the street there are comments that all of this will require consolidation into large com-

panies who can afford to deal with the regulations and that this will drive prices up for the average user of herbal remedies. Consumers for Health Choice in the U.K. has this to say about the amendments to the Directive: "The European Union is currently considering a proposal to amend the main EU laws defining a medicinal product and setting out the licensing system for such products. An exercise initially intended to be a "tidying up" of the law, has been hijacked by the pharmaceutical industry which is seeking amendments to the definitions of a medicinal product and to the scope of this Directive which, if accepted, would allow medicines regulators to insist that many food supplements were legally medicines requiring a licence even if they are intended to be covered by other EU directives which define them as food products."

"This would lead at best to confusion about which regulations applied to which products, and at worst could lead to perfectly legal and safe food supplements suddenly being reclassified as medicines having to comply with expensive and inappropriate licensing requirements intended for pharmaceutical drugs." [www.healthchoice.org.uk](http://www.healthchoice.org.uk)

The large volume of amendments recently adopted and the difficulties of merging all of the requirements means that suspicions may continue about the intentions of the amendments and sow seeds of discontent for some months to come.

Some consumers believe these amendments are being forced by the pharmaceutical industry, while others acquiesce in changes for safety and other reasons, believing more scientific information is available now.

## NEW ADVICE ON SAFETY OF VITAMINS & MINERALS

UK's Food Standards Agency on May 8, 2003 issued new advice about vitamins and minerals, saying the amounts of most vitamins and minerals that people take are not thought to be harmful, but the Agency is now advising the public on what levels of supplements are unlikely to cause any harm.

The Agency is advising people not to take chromium picolinate and has consulted on a proposal to ban the use of this form of chromium in the manufacture of food supplements because there is a chance that it could cause cancer.

Having 10 mg or less a day of chromium in other forms from food and supplements is unlikely to cause any harm.

Some substances may have irreversible harmful effects if taken for long periods at the highest supplemental doses. These include beta-carotene (especially for smokers and people who have been exposed to asbestos), nicotinic acid, zinc, manganese (especially for older people) and phosphorus.

Levels of vitamin C above 1000 mg a day could cause abdominal pain and diarrhoea. Similarly, high intakes of calcium (above 1500 mg a day) and iron (above 17 mg a day) may result in similar symptoms in some people. However, these symptoms should disappear once people stop taking the supplements.

The Agency is also re-emphasising its advice that people should not take more than 10 mg a day of vitamin B6

from food supplements unless acting on medical advice. Taking large amounts for a long time can lead to a loss of feeling in the arms and legs. Generally these symptoms are reversible but in a few cases the effect has been irreversible.

This advice follows the publication of the report of the Expert Group on Vitamins and Minerals (EVM), an independent expert advisory committee that has made recommendations on 31 vitamins and minerals.

The EVM has assessed the available evidence on safety, in response to concern over possible risks of taking high doses of vitamins and minerals.

Current intakes of most vitamins and minerals are not thought to be harmful. However, the Food Standards Agency has said one substance may have the potential to cause cancer and has consulted on a proposal to ban its use; six substances may have irreversible effects if taken in large amounts over long periods of time; and three substances may have short-term harmful effects, which would disappear if people stopped taking the supplement.

In more detail:

- Chromium in the form of chromium picolinate may have the potential to cause cancer; consumers are advised not to take chromium in this form. The FSA has consulted on a proposal to ban its use in the manufacture of food supplements. Having 10mg/day or less in total of chromium in other forms is unlikely to cause any harm.

- Levels of vitamin C above 1000mg/day could cause abdominal pain and diarrhoea. Similarly, high intakes of calcium (above 1500mg/day) and iron (above 17mg/day) may result in similar symptoms in some people. These symptoms should disappear once people stop taking the supplements.
- There are some substances that may have irreversible harmful effects if taken for long periods at the highest supplemental doses. These include beta-carotene (especially for smokers and those exposed to asbestos), nicotinic acid, zinc, manganese (especially for older people) and phosphorus.
- Current advice on vitamin B6 is being re-emphasised. The Agency advises against taking more than 10mg/day of vitamin B6 from dietary supplements unless acting on medical advice. High intakes taken over a long period of time can lead to a loss of feeling in the arms and legs.

Advice is also being given on biotin, folic acid, pantothenic acid, riboflavin, niacin, thiamin, vitamin B12, vitamin D, vitamin E, vitamin K, boron, cobalt, copper, iodine, molybdenum, nickel, selenium, tin, magnesium, potassium, and silicon.

Sir John Krebs, Chair of the Food Standards Agency, said: "While in most cases you can get all the nutrients you need from a balanced diet, many people choose to take supplements. But taking some high dose

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Jim Chao, Manager, was not signed. FDA responded on April 2, 2003, saying that the regulations at 21 CFR 101.93(a)(3) required the letter to be signed by a responsible individual who can certify the accuracy of the information. Since the letter was not signed, the company was told it had not complied with the requirements of the law. Dkt. No. 97S-0163, Ltr. 686.

**National Vitamin Company, Inc.** of Porterville, California, sent five letter notices to FDA between February 17, 2003 and March 12, 2003, all received at FDA on March 19, 2003. These letters gave notice for structure/function claims for: 1) Cayenne Pepper 450mg capsules with the claim “*The Cayenne Pepper may help with gastrointestinal disorders, muscle spasms, and rheumatic conditions;*” 2) for Flaxseed Oil 1000 mg, containing 1000 mg Flaxseed Oil, Omega-3 at 570mg, Omega-6 at 160 mg, and

Omega-9 at 180 mg. Per softgel with the claim “*Flaxseed oil (Linum Usitatissimum) provides essential fatty acids, including Omega 6 as Gamma Linoleic acid which helps to maintain healthy joint function by inhibiting the body’s inflammatory response as well as helping to support healthy cholesterol and Triglyceride levels for health heart;*” (Sic) 3) for Cholesterol Fighter, containing Inositol Niacinate 37.5 mg, Trimethylglycine 250 mg, Chitosan 100 mg, Beta-Sitosterol Complex 50 mg and Lecithin 50 mg, all per capsule, with the claim “*Cholesterol Fighter is specially formulated from the finest quality herbs and ingredients including Betaine Anthdrous – known as Trimethylglycine and natural Chiosan – Shell Fish Fiber. Cholesterol Fighter is intended for use by healthy adults whose goal is to maintain a healthy cholesterol profile;*” 4) for Nature’s Blend Cold & Flu Fighter, containing Ascorbic Acid 30 mg, Elderberry Standardized Extract Flavanoids 5% & Polyphenols 15% at 100 mg, St. John’s Wort Standardized Extract Hypericin 0.3% at 75 mg, Echinacea Standardized Extract Total Phenols 4% at 50 mg, Cat’s Claw bark at 25 mg, Golden Seal Root at 25 mg, and Siberian Ginseng root at 25 mg, all per capsule with the claim “*The pure and natural unique blend of powders and standardized herbal extracts are formulated to stimulate the body’s immune system. The stimulation may provide mild antibiotic and antiviral activities that could help resist infections;*” and 5) for Echinacea 350 mg & Golden Seal 100 mg capsules with the claim “*Echinacea increases the body’s natural immune system and Gold Seal may help fight infections.*” FDA responded on April 2, 2003

identifying portions of the claims for Cayenne 450 mg, namely, “... *rheumatic conditions...*,” for Echinacea 350 mg & Golden Seal 100 mg, namely, “... *Golden Seal may help fight infections;*” and for Cold & Flu Fighter, namely, “... *may provide mild antibiotic and antiviral activities that could help resist infections;*” but the agency letter signed by Susan J. Walker, M.D. made no comments about these particular claims. Instead, the letter continued to mention the claims for Cholesterol Fighter, namely, “... *maintain a healthy cholesterol profile;*” and the claim for Flaxseed Oil 1000 mg, namely, “... *support healthy cholesterol ... levels for healthy heart*” were implied health claims because they did not clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, in the case the latter two products, they will be treated as drugs under the Act. Dkt. No. 97S-0197, Ltr. 687.

**AuMed, Inc.** of Valley Cottage, New York, whose letterhead motto is “The Gold Standard in Health Care,” sent a notice letter to FDA on October 28, 2002 that its health professional literature, not product labels, would contain certain claims for five different products. The letter was not signed by its purported author, Arun Chainani, M.D. Also enclosed were product labels and reference literature. FDA responded on April 7, 2003 first saying that since the letter is not signed, the notice is not effective. Then continuing without mentioning the label for CORMED, a multivitamin, the agency letter said that the reference literature for the products Youthmed, Glucomed,

See SECTION 403 LETTERS - on p. 9...

**SECTION 403 LETTERS**--*Cont'd from p. 8...* Hartmed, and Ostemed all contained numerous references to the use of the products and/or their ingredients in the treatment, prevention, cure, or mitigation of diseases. Because of these statements, FDA concluded these products would be drugs and would not qualify as structure/function claims under the Act. Dkt. No. 97S-0163, Ltr. 688.

**Novartis Ophthalmics** of Atlanta Georgia, wrote FDA on April 1, 2003, concerning claims it would make for its product Vitalux™ Eye Vitamin and Mineral Supplement, containing beta-carotene 12,500 IU, ascorbic acid 250 mg, vitamin E 200 IU, zinc gluconate 40 mg, selenium 50 mcg, copper 1 mg, lutein 3 mg, and Zeaxanthin 0.2%. The label of the product indicated that it was made in Canada for Novartis Ophthalmics of Duluth, Georgia. FDA responded on April 10, 2003, saying that the following claims were not structure/function claims, but rather disease claims for macular degeneration. The claims were: "... contains ... found to be beneficial to eye health by the Age-Related Eye Disease Study...;" "... the leader in the fight against Age-Related Macular Degeneration (AMD). Novartis Ophthalmics continues to research treatment for AMD...;" and "From the leaders in the fight against AMD." Dkt. No. 97S-0163, Ltr. 689.

**National Vitamin Company** of Porterville, California, wrote FDA on March 13, 17 and 26, 2003, to give

notice of claims it would use for St. John's Wort Standardized Extract 300 mg, Hawthorne Berry 450 mg, and Glucosamine Sulfate 500 mg. FDA responded on April 10, 2003 saying that the following portions of claims made the products into drugs. For St. John's Wort – "work as antidepressant;" Hawthorne – "... help dilate peripheral and coronary blood vessels;" and Glucosamine – "... reduce osteoarthritic pain by slowing cartilage deterioration." Dkt. No. 97S-0163, Ltr. 690.

**Herbalist & Alchemist, Inc.** of Washington, New Jersey, wrote FDA on March 27, 2003 to give notice that it would use certain claims for the product Sinus Allergy Support, containing echinacea purpurea root, osha, eyebright, horseradish and bayberry. The claim was "Herbal Support When Allergens Are Present." The company said it had submitted the product under the name Eyebright/Osha Compound on April 20, 2000, and has now changed the product name. FDA responded on April 10, 2003 stating that the proposed claim is to treat a class of diseases, namely, allergies, and therefore the product is a drug and not a dietary supplement. Dkt. No. 97S-0163, Ltr. 691.

**Prostate Rx, Inc.** of Naples, Florida, wrote FDA on March 13, 2003, giving notice that it was using certain claims for its product, Prostate Rx®, containing 320 mg of 100% pure standardized premium liquid extract of saw palmetto. The label containing three panels was enclosed with the notice letter. FDA responded on April 10, 2003, saying the following label statements were not structure/function claims, but rather were disease claims for benign prostatic hypertrophy: "... Most

men experience a gradual increase in prostate size at some time after middle age ... an enlarged prostate can lead to an obstruction of urinary flow. For many men, this can mean discomfort in urination or increased night time urination... Clinical studies show using standardized liquid extract may promote prostate relief from these symptoms." These statements make the product a drug. It would not be a dietary supplement if these statements are used. Dkt. No. 97S-0163, Ltr. 692.

**Oregon's Wild Harvest** of Sandy, Oregon, wrote FDA on April 2, 2003, stating that it would use certain claims for two products: Gymnema – "Supports Maintenance of Healthy Sugar Levels" and Aller-Aid – no claim. FDA responded on April 14, 2003 saying that the revised claim for Gymnema does not completely address the previous agency objections as it does not make clear that the claims are about healthy blood glucose levels that are already within normal limits. The product still bears claims that the product is intended to treat disease, namely, diabetes. Previously Aller-Aid claimed "Allergy Symptom Support." Dkt. No. 97S-0163, Ltr. 693.

**Taisho Pharmaceutical California, Inc.** wrote FDA on April 2, 2003, through its attorney, Covington & Burling (Jeannie M. Perron, Esq), to respond to FDA's letter of March 19, 2003, previously objecting to certain claims for Lipovitan® Sustained Energy Formula, Lipovitan® Healthy Joint Formula, and Lipovitan® Healthy Heart Formula. In the new letter Attorney Perron said the company would accept amend-

See SECTION 403 LETTERS -- on page 16...

## GOLDENSEAL TRADEMARKS

Only eight records are available for Goldenseal products at the U.S. Patent and Trademark Office and half are dead marks and two of the live marks are not for a botanical product. Here are the marks starting with the live mark.

**Golden Seal®** is a registered mark, Registration No. 2152264, in International Class 037, for installation, repair and maintenance of heating and air conditioning equipment, by Golden Seal Heating & Air Conditioning, Inc. of St. Charles, Illinois. The mark was registered April 28, 1998 as a service mark. The mark was first used February 25, 1985.

**Echinaceae-Golden Seal Power®** is a registered mark, Registration No. 1919220, in International Class 005, by Natur-Pharma, Inc. DBA Nature's Herbs, of American Fork, Utah, for vitamins and dietary food supplements. The mark was registered September 19, 1995 and was first used August 16, 1994. The mark was assigned to Twin Laboratories, Inc., of Ronkonkoma, New York and Section 8 and 15 affidavits have been accepted and acknowledged.

**Golden Seal-Power®** is a registered mark, Registration No. 1917588, in International Class 005, by Natur-Pharma, Inc. DBA Nature's Herbs, of American Fork, Utah, for vitamins and dietary food supplements. The mark was registered September 19, 1995 and was first used August 16, 1994. The mark was assigned to Twin Laboratories, Inc., of Ronkonkoma, New York and Section 8 and 15 affidavits have been accepted and acknowledged.

**Golden Brand®** is a registered mark, Registration No. 1718168, in International Class 032, for mattresses, by Sino-In Trading, Inc. of Temple City, California. The mark was first used May 11, 1990 and is a design mark found under search codes 240707 and 280103. The English translation of the Chinese characters in the mark is for the characters in the seal "gold plate" and for the characters above the seal "gold plate and design or mark." The mark was registered September 22, 1992 and disclaims the exclusive right to use the word "brand" apart from the mark as shown. A section 8 affidavit was filed and accepted.

**Golden Seal** is a cancelled mark from International Class 003 for non-medicated hair care preparations;

namely, conditioner/reconstructor, by Redmond Products, Inc. DBA Holistic Labs, of Chanhassen, Minnesota. The mark was registered as Registration No. 1714898, on September 15, 1992, and first used March 20, 1907, but cancelled under Section 8 for failure to file an affidavit of use.

**Golden Seal Xtra** was filed March 16, 1998 as an intent to use mark by Rexall Sundown, Inc, of Boca Raton, Florida, for vitamins, minerals, dietary and nutritional supplements all containing Golden Seal in International Class 005. The mark can be found at Serial No. 75451211. After publication for opposition on February 23, 1999, the mark was abandoned November 19, 2000 by the applicant for failure to file a statement of use after Notice of Allowance was issued. There was a disclaimer to the exclusive right to use the term "golden seal" apart from the mark as shown.

**Golden Seal Root Xtra** was filed March 16, 1998 as an intent to use mark by Rexall Sundown, Inc, of Boca Raton, Florida, for vitamins, minerals, dietary and nutritional supplements all containing Golden Seal in International Class 005. The mark can be found at Serial No. 75451210. After publication for opposition on February 23, 1999, the mark was abandoned November 19, 2000 by the applicant for failure to file a statement of use after Notice of Allowance was issued. There was a disclaimer to the exclusive right to use the term "golden seal" apart from the mark as shown.

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## LOBELIA TRADEMARKS

Another infrequently trademarked botanical is lobelia. There are only two dead marks and one live one at the present.

**Lobelia White Palace®** is registered, Registration No. 1738550, for lobelia flower seeds, in International Class 031, by John Bodger & Sons Co., DBA Bodger Seeds, Ltd., an Elmonte, California company. There is a disclaimer for "lobelia white" apart from the mark as shown. The mark was first used October 31, 1991 and registered on December 8, 1992. Section 8 and 15 affidavit was accepted and acknowledged and the mark was renewed March 21, 2003.

See LOBELIA -- Continued on page 11...

LOBELIA TRADEMARKS - Continued from page 10...

**Syrup Lobelia and Tolu Compound** was filed as an intent to use mark on August 7, 2000, for pharmaceutical preparations made with cannabis sativa L., for use as treatment in cough, expectorant, asthma, bronchitis, emphysema, by Classic Pharmaceuticals of Berkeley, California in International Class 005. The mark was abandoned for failure to respond to an office action on October 24, 2001.

**Lobelia** is a dead mark that was filed as an intent to use mark on November 27, 1991 for white oils for used involving food contact, for hydraulic systems, for lubrication of small and delicate mechanisms, and for lubrication of food industry materials by Total Coporation of Puteaux, France, in International Class 004. The mark was abandoned August 5, 1995 for failure to file a statement of use after the Notice of Allowance was issued.

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### FTC REQUIRES SCIENTIFIC EVIDENCE FOR “Snore Formula” CLAIMS

The Federal Trade Commission announced that an Arizona-based company, Snore Formula, Inc., its officers, and a distributor have agreed to settle Federal Trade Commission charges that they failed to have scientific substantiation for the claims made for “Dr. Harris’ Original Snore Formula” (Snore Formula) tablets. Snore Formula is an herbal supplement purported to cure snoring. The Commission’s complaint charges that the respondents made unsubstantiated claims about the tablets’ efficacy in preventing sleep apnea in adult and child users and significantly reducing snoring. The Commission accepted the consent agreement subject to public comment. It requires that the respondents possess competent and reliable scientific evidence to substantiate representations that Snore Formula or any other food, drug, device, service, or dietary supplement prevents, treats, eliminates, or reduces snoring and sleep apnea in both adult or child users.

The FTC charges Ronald General and Dennis H. Harris, M.D., and their company, Snore Formula, Inc., with violating the FTC Act by failing to possess evidence substantiating their claims for Snore Formula. The FTC also charged Snore Formula distributor Gerald L. “Jerry” Harris, owner of the SnoreFormula.com Web site. According to the FTC’s complaint, the respondents failed to have a reasonable basis for claims they made about

their product’s efficacy in: preventing sleep apnea in adult and child users who would otherwise develop sleep apnea; treating the “early stages” of sleep apnea; and eliminating, preventing, or significantly reducing snoring. The complaint alleges that the respondents failed to disclose the importance of seeing a physician for people who have symptoms of sleep apnea because the condition may be fatal. The complaint further alleges that the respondents falsely claimed that scientific testing demonstrates that the tablets eliminate, prevent, or significantly reduce snoring in 86 percent of users.

In addition, the FTC alleges that Dennis H. Harris, M.D., acting as an expert endorser for the product, misrepresented that he had sufficiently exercised his purported expertise to determine the accuracy of his claims for the product.

The consent agreement to settle the charges requires the respondents to have scientific evidence for any future claims about the effect of any food, drug, device, service, or dietary supplement on the structure or function of the human body, or about any other health benefit, or the safety, of any such product or service. The consent agreement also requires the respondents to disclose clearly and prominently that the product is not intended to treat sleep apnea and to provide a warning statement for consumers with symptoms of sleep apnea to see a physician or a specialist in sleep medicine. These disclosures must be made whenever the respondents represent that a product not shown to treat sleep apnea can eliminate, prevent, or reduce snoring.

The consent agreement prohibits Snore Formula, Inc. and its officers from providing the “means and instrumentalities” to others to make claims without scientific support about the benefits, performance, efficacy, or safety of any food, drug, device, service, or dietary supplement.

In addition, the consent agreement requires that Dennis H. Harris, M.D., sufficiently examine or test products that he endorses as an expert. Further, the proposed

See SNORE FORMULA-- Continued on page 12...

[www.NatMedLaw.com](http://www.NatMedLaw.com)



Photo Courtesy of Lloyd Library and Museum

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#### SNORE FORMULA -- from page 11...

settlement requires the company and its officers to disseminate a copy of the order to its past and future distributors, and requires them to monitor their distributors and terminate any distributor who continues to make prohibited claims. Finally, the consent order contains standard record keeping requirements to allow the agency to monitor the respondents' compliance with the order.

The FTC vote to accept the proposed consent agreement was 5-0. The proposed consent agreement will be subject to public comment for 30 days, until May 15, 2003, after which the Commission will decide whether to make it final. Comments should be addressed to the FTC, Office of the Secretary, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

NML learned one hand written comment was received by FTC on or about May 15, but the decision is still open on July 1.

#### FTC CHARGES --Continued from page 2...

Huang. The FTC alleges that HLNA made numerous false and unsubstantiated weight-loss claims for Berry Trim Plus through testimonials such as, "Teacher Loses 70 lbs. In Only 8 Weeks Easily," and other statements. The FTC alleges that the HLNA defendants falsely represented that Berry Trim Plus products cause rapid and substantial weight loss, including as much as 70 pounds in eight weeks, without dieting or increasing exercise, and that clinical studies prove that Berry Trim Plus causes rapid and substantial weight loss. The FTC complaint further alleges that the defendants did not have a reasonable basis to advertise that Berry Trim Plus is "100% safe" and "perfectly safe" to use, and that it prevents fat absorption from whatever the user eats.

The HLNA settlement order prohibits the defendants from making false and unsubstantiated weight-loss claims, as well as unsubstantiated safety claims. The order also prohibits the defendants from misrepresenting the contents, validity, results, conclusions, or interpretations of any test or study. The order requires that a prominent warning about health risks be made in any advertisement, promotional item, or product label for an ephedra product. The warning includes information that ephedra use can result in serious injury, and even death. The order requires HLNA to pay \$195,000 in consumer redress. If, however, the defendants have made any material misrepresentation or omission on their financial statements, the court may enter a \$35 million judgment against them.

#### USA Pharmacal Sales, Inc.

The FTC's complaint names USA Pharmacal Sales, Inc., and its co-owners, John Pence and Arthur

Sussman. The defendants, based in Palm Harbor, Florida, marketed and sold three weight-loss products and an erectile dysfunction supplement. The META-BIOLOGICAL weight-loss cocktail contains ephedrine alkaloids derived from Ma Huang, caffeine, and 19 other ingredients. FAT•SPONGE IN A PILL is comprised of chitosan and glucomannan, and digestive aids for lactose-intolerant people. CALOTROL/MD contains chitosan, gymnema sylvestre, HCA, and chromium picolinate. The erectile dysfunction supplement, VIRILE V, contains yohimbine, androstenedione (a steroid hormone), and 12 other active ingredients. According to the FTC, the defendants advertised their weight loss and erectile dysfunction products through free-standing inserts in regional newspapers and direct mail. The defendants also used an expert medical endorser in some advertisements to tout their products' efficacy and safety.

The FTC's complaint alleges that advertisements for the purported weight-loss products made false claims that the products cause rapid, substantial, and permanent weight loss without the need to reduce caloric intake. The complaint also alleges that the ads made false claims that "clinical tests" or "medical research" proves that the products cause rapid, significant, or permanent weight loss. The complaint further alleges that the defendants made unsubstantiated claims that the META-BIOLOGICAL ephedra weight-loss product is safe. In addition, the FTC alleges that the defendants made deceptive efficacy and safety claims for the erectile dysfunction supplement. According to the FTC, there is no reliable evidence to suggest that ephe-

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**FTC CHARGES--** *from page 12...*  
 dra, an ingredient in META-BIOLOGICAL, or androstenedione and yohimbe, ingredients in VIRILE V, are safe. In fact, the complaint alleges that they have been associated with health risks.

The USA Pharmacal settlement order prohibits the defendants from making false or unsubstantiated claims that the weight-loss products or any substantially similar product causes rapid, substantial, or permanent weight loss or fat loss. The order also bars them from representing that clinical or medical studies support such claims. The order requires that the defendants place a prominent warning about health risks in any advertisement, promotional item, or product label for an ephedra product. The warning includes information that ephedra use can result in serious injury, and even death. USA Pharmacal likewise must place health risk warnings on materials that make claims for any products that contain yohimbe or androgen.

USA Pharmacal has agreed to pay \$175,000 in consumer redress. If, however, the defendants have made any material misrepresentation or omission on their financial statements, the court may enter a judgment for \$9.2 million against them.

Both the HLNA and USA Pharmacal settlements require the defendants to take reasonable steps to monitor and ensure that all employees and agents comply with the order, and to terminate any employee who knowingly violates the order. Also, both settlements contain various recordkeeping requirements to assist the FTC in monitoring the defendants' compliance.

The Commission vote to authorize the staff to file the complaint and

stipulated final judgment in the HLNA case was 5-0. The documents are being filed in the U.S. District Court for the District of Columbia.

The Commission vote to authorize the staff to file the complaint and stipulated final judgment in the USA Pharmacal case was 5-0. The documents are being filed in the U.S. District court for the Middle District of Florida, Tampa Division.

(FTC Docket No. C-3459 (Levey/Bentley); Civil Action No. CV-03-4670 GAF (AJWx) (FTC File No. 012-3099 (Health Labs); Civil Action No. not available at press time) (FTC File No. 002-3319 (USA Pharmacal); Civil Action No. not available at press time)

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**FTC/FDA ACTIONS --** *from page 1...*

rosis and heart disease. The FTC charges that these and other claims go far beyond existing scientific evidence regarding the recognized health benefits of calcium.

The defendants promote the product primarily through a nationally televised 30-minute infomercial featuring Trudeau and Barefoot, and through statements made in brochures accompanying the product. The infomercial has aired on cable channels such as Women's Entertainment, Comedy Central, the Discovery Channel, and Bravo. "The Commission has voiced strong concerns about deceptive claims for dietary supplements," said Howard Beales, Director of the FTC's Bureau of Consumer Protection. "These cases demonstrate that the FTC will take aggressive enforcement action, particularly when, as alleged in this case, the products are marketed as cures for serious diseases like cancer and heart disease.

Marketers who step over the line will find themselves between a rock and a hard place."

In a separate action, the FTC has charged one of the defendants, Kevin Trudeau, with violating a 1998 federal district court order that prohibits him from making unsubstantiated claims about the benefits, performance, or efficacy of any products. The FTC alleges that Trudeau violated that order by making false and unsubstantiated claims about Coral Calcium Supreme, and by making unsubstantiated claims that another product, Biotape, provides significant or permanent relief from severe pain, including debilitating back pain, and pain from arthritis, sciatica, and migraines. In both of these actions, the FTC has asked the court for a temporary restraining order that would prohibit the defendants from making the challenged claims and would freeze their assets.

In related law enforcement efforts, the FTC and the FDA are sending strong warning letters to Web site operators who are marketing coral calcium products claiming that coral calcium is an effective treatment or cure for cancer and/or other diseases. In dozens of warnings sent this week, the FTC states it is aware of no competent and reliable scientific evidence supporting such claims and that such unsupported claims are unlawful under the FTC Act. Accordingly, the FTC is instructing the Web site operators to remove any false or deceptive claims from their sites immediately. In a similar action, the FDA warned Web site operators that disease claims and unsubstantiated structure/function claims cause their products to be in violation of the Fed-

*See FTC/FDA ACTIONS -- on page 14...*

FTC/FDA ACTIONS -- Continued from page 13...  
 eral Food, Drug, and Cosmetic Act.

“FDA and FTC are working together to maximize our efforts to combat health fraud,” said FDA Commissioner Mark B. McClellan. “We are trying to be particularly vigilant concerning fraudulent internet promotion, because this is emerging as an increasingly insidious way of trying to exploit the public.”

### **FTC v. Kevin Trudeau, Robert Barefoot, Shop America (USA), LLC, and Deonna Enterprises**

The FTC’s first action alleges that Kevin Trudeau, Robert Barefoot, Shop America (USA), LLC, and Deonna Enterprises, Inc., violated the FTC Act by claiming, falsely and without substantiation, that Coral Calcium Supreme can treat or cure cancer and other diseases such as multiple sclerosis and heart disease. According to the FTC, Coral Calcium Supreme is a dietary supplement purportedly comprised of marine coral from Okinawa, Japan. A one-month supply of the product (90 capsules) costs \$19.95.

The FTC’s complaint alleges that the defendants claim, falsely and without substantiation, that Coral Calcium Supreme will treat and/or cure all forms of cancer and other diseases such as multiple sclerosis, lupus, heart disease, and chronic high blood pressure. The complaint also alleges that the defendants falsely claim that scientific research published in reputable medical journals proves that calcium supplements can reverse and/or cure all forms of cancer. Finally, the complaint challenges the defendants’ claims that a daily serving of Coral Calcium Supreme provides the same amount of bioavailable calcium as two gallons of milk, and that the body absorbs significantly more of the calcium in coral calcium - up to 100 times more, and at a significantly faster rate - than the calcium contained in commonly available calcium supplements.

The FTC is seeking preliminary and permanent injunctive relief, including restitution to consumers who purchased Coral Calcium Supreme. In addition, the FTC has asked the court for a temporary restraining order that would prohibit the defendants from making the challenged claims, and would freeze their assets.

### **FTC v. Kevin Trudeau**

The FTC’s second action, against Trudeau alone, alleges that Trudeau violated a 1998 FTC order prohibiting him from making unsubstantiated claims about the benefits, performance, or efficacy of any product. The FTC alleges that Trudeau violated the order by making false and unsubstantiated claims about Coral Calcium Supreme, and also by making unsubstantiated claims about Biotape. According to the FTC, Biotape is a purported pain-relief product which Trudeau promotes through a separate infomercial, which has aired on national cable channels such as PAX Television, the Hallmark Channel, and E! Entertainment Television. Consumers are instructed to place a strip of Biotape directly on the parts of their bodies where they feel pain. One sheet of Biotape, containing 10 strips, costs approximately \$10. In this action, the FTC is seeking a finding of contempt, monetary relief, and other injunctive relief, as well as a temporary restraining order that would prohibit Trudeau from making the challenged claims, and would freeze his assets.

### **Warning Letters**

In addition to the FTC’s federal court actions, the Commission is sending warning letters to dozens of Web site operators who are making similar claims for coral calcium products. In the warning letters, the FTC reminds the Web site operators that any claim that coral calcium is an effective treatment or cure for any disease must be supported by competent and reliable scientific evidence to comply with the law. The FTC states it is aware of no such evidence supporting these claims, and that without the required support, the claims are illegal under the FTC Act. Accordingly, the FTC is instructing the Web site operators to remove any false or deceptive claims from their sites immediately.

In a similar action, the FDA issued warning letters to numerous Web site operators who are promoting coral calcium on the Internet. The letters cited the organizations for representing the products as useful in the prevention or treatment of serious diseases. In addition, a majority of the letters also cited the firms for making unsubstantiated claims regarding the effect of their products on the structure or function of the body. The FDA letters warn the recipients that FDA may initiate further enforcement action if the violations are not corrected.

The FTC and FDA had conducted Internet “surfs”

See FTC/FDA ACTIONS on page 15...

FTC/FDA ACTIONS --Continued from page 14...

and found numerous Web sites touting coral calcium products as an effective treatment or cure for cancer and other diseases such as lupus, multiple sclerosis, and heart disease. The staffs of the two agencies will follow up by revisiting the target sites to determine whether the Web site operators have deleted or revised the unproven claims.

The FTC vote to authorize filing of the cases was 5-0. The cases were filed in the U.S. District Court for the Northern District of Illinois, Eastern Division, on June 9, 2003. (FTC File No. (Coral Calcium) 032 3064; Civil Action No. 03 C 904) (FTC File No. (Trudeau) X980014; Civil Action No. 98 C )

ADVICE ON VITAMINS -- Cont'd from page 7...

supplements over a long period of time could be harmful. We are using an extremely thorough independent expert review of the scientific evidence on the safety of vitamins and minerals as the basis for new advice to help consumers make informed choices. In addition, the Board of the Food Standards Agency will be considering what further action we would wish the supplements industry to take."

The FSA Board will receive a report recommending voluntary action by the supplements industry to reduce the dose and/or provide label warnings for some high dose food supplements.

The Expert Group on Vitamins and Minerals carried out a detailed nutritional and toxicological review of 34 vitamins and minerals, with particular reference to safety in long-term use. Safe upper levels were suggested for eight of them, guidance suggested for 23, and statements were issued for three minerals. Guidance was given where there was not enough evidence to suggest a safe upper level for a particular vitamin or mineral. Guidance and safe upper levels were set for total intake from food, supplements, or a combination of the two.

The EVM is an independent group made up of 11 members from the medical and scientific community, one lay member, and four observers representing consumer organisations, the health and food industries, and alternative medicine interests.

Supplements are recommended for certain groups of

people:

Women of child bearing age and pregnant women (until the 12th week of pregnancy) should take a daily dietary supplement of 0.4mg folic acid and eat plenty of folate-rich foods in order to reduce the risk of neural tube defects in their babies.

- Some women with high menstrual blood losses may need to take iron supplements, as advised by their GP.
- If you are pregnant or breastfeeding, you should take supplements containing 10 micrograms (0.01mg) of vitamin D per day. Some older people may need to consider taking vitamin D as advised by their GP.
- Pregnant women, or women who are thinking of becoming pregnant, should not take supplements of vitamin A, except on the advice of their GP. This is because there is an association between very high levels of retinol (a source of vitamin A) consumption during pregnancy and the incidence of some birth defects. As an additional precaution, pregnant women should not eat liver or liver products as these are a very rich source of retinol.
- From the age of six months to two years (or five if they are not eating a wide enough range of foods), most young children will benefit from vitamin drops (A, C, and D). These are available free of charge from health clinics for children under five years of age in families receiving Income Support or an income-based Job Seekers Al-

See ADVICE ON VITAMINS -- 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

**SECTION 403 LETTERS** -- from page 9...  
 ing the claim to: *Taurine – Helps the body regulate cholesterol levels which are already within the normal range.*” The Attorney stated her client disagreed with FDA’s interpretation, but would do this in the interest of settling the matter. FDA responded on April 14, 2003, stating that the new claim resolves the issued raised in the March 19, 2003 letter. Dkt. No. 97S-0163, Ltr. 694.

**ADVICE ON VITAMINS** -- from page 15...

lowance.

A varied and balanced diet, which includes plenty of fruit, vegetables, and starchy foods, and moderate amounts of dairy products, meat, fish, and meat alternatives will provide all the nutrients that most people need without having to take supplements.

The EMV May 2003 Report is a 360-page document. It treats all the 34 vitamin and minerals covered with great detail. The Report is available on the Food Standards Agency web site. To give some idea of the kind of risk assessment the Panel produced for a vitamin, here are the words used to summarize the Panel’s thoughts about folic acid:

#### **RISK ASSESSMENT**

Folic acid is generally considered as safe in therapeutic use. Adverse effects may, potentially, occur in specific groups, such as individuals being treated with drugs that interact with folic acid metabolism. Women at risk of a NTD-affected pregnancy appear to be able to take folate supplements at up to 4 mg/day, without adverse reproductive or developmental effects. Folic acid may lead to reversal of the symptoms of vitamin B12 deficiency, potentially allowing the neuropathy associated with vitamin B12 deficiency to

develop untreated. Vitamin B12 deficiency is most prevalent in older people. Few data are available from toxicological studies of folates in animals.

#### **ESTABLISHMENT OF GUIDANCE LEVEL**

There are insufficient data from animal or human studies to establish a Safe Upper Level for folic acid. COMA recommended that, for the prevention of foetal NTDs, women who could become pregnant should take a 0.40 mg folic acid supplement daily, in addition to normal dietary folate intake, until the 12th week of pregnancy. Women in highrisk groups may be advised to take up to 10 times this level of supplementation.

We are aware of evidence that increased folate acid intake lowers serum homocysteine levels and may potentially help prevent adverse cardiovascular events. However, consideration of such effects is not within the remit of the EVM. We are also aware of recent studies which have suggested that increased folate intake may increase the incidence of multiple births. We note that this is an area of potential concern, but that there is currently no substantive evidence for such an effect.

The main concern regarding ingestion of excess folic acid is the consequential masking of vitamin B12 deficiency. A general consistency of data indicates that supplementation with >1 mg/day folic acid does not mask vitamin B12-associated anaemia in the majority of subjects, whereas supplementation with <5 mg/day folic acid does. The effects of doses of between 1 and 5 mg/day are unclear. No other significant adverse effects have been associated with ingestion of folic acid.

For guidance purposes only, in the general population a supplemental dose of 1 mg/day (equivalent to 0.017 mg/kg bw/day in a 60 kg adult) would not be expected to cause adverse effects. Because of the consistency of the data, from a large number of studies in humans, no uncertainty factors have been applied. Assuming a maximum intake from food of approximately 0.49 mg/



Photo Courtesy of Lloyd Library and Museum

day, a total dose of 1.5 mg/day (equivalent to 0.025 mg/kg bw/day in a 60 kg adult) would not be expected to have any adverse effects. [www.foodstandards.gov.uk](http://www.foodstandards.gov.uk)

Back in January 2001, the Institute of Medicine in the U.S. determined that an Adequate Intake of Chromium was 35 mcg for men and 25 mcg for women. No upper limit was set by the U.S. group.

“Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc” [www.nap.edu](http://www.nap.edu)

**PRESIDENT ASKS** -- Cont'd from p. 1...

*Food Guide Pyramid*, which was introduced in 1992.

“Secretary Thompson has made it clear that both childhood overweight and adult obesity and the associated chronic health problems such as heart disease are widespread in the United

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States, and have become one of our nation's most important public health problems. However, recent studies suggest that adherence to the *Dietary Guidelines* has only modest impact on the risk of cardiovascular disease and no significant impact on other chronic diseases such as cancer. The Office of Management and Budget (OMB) believes that these and other studies should play a prominent role as USDA and HHS revise the guidelines. Given the wide reach of the federal nutrition guidelines, we believe that good nutrition habits fostered by improved information on the links between diet and health will have a significant health impact, especially in reducing heart disease. Coronary heart disease (CHD) is our nation's largest cause of premature death for both men and women, killing over 500,000 Americans each year. Even a modest improvement in dietary habits may lead to significant reductions in the number of premature deaths from CHD.

"We recognize that the 2000 *Dietary Guidelines* made some changes in recommendations that may reduce cardiovascular risk. We nonetheless urge you to reconsider all available nutritional and medical evidence as you develop the new guidelines. For example, in a previous letter addressed to HHS, we encouraged the Food and Drug Administration (FDA) to finalize a rule to require a product's Nutrition Facts panel to include the amount of *trans* fatty acids present in foods. As you know, there is a growing body of scientific evidence, both experimental and epidemiological, that suggests consumption of *trans* fatty acids increases the risk of CHD. Another important risk factor is the omega-3 fatty acid content of food. Both epidemiologic and clinical studies find that an increase in consumption of omega-3 fatty acids results in reduced deaths due to CHD. The recent revision of the American Heart Association's (AHA's) dietary guidelines recognizes this evidence by recommending con-

suming fish, which is high in omega-3 fatty acids, at least twice weekly to reduce the risk of CHD. In addition, the AHA recommends the inclusion of oils and other food sources high in omega-3 fatty acids.

"The current *Dietary Guidelines* targets only the reduction of saturated fat and cholesterol, with only a brief reference to the risks from *trans* fatty acids and benefits of omega-3 fatty acids. We encourage you to consider strengthening the language in the guidance and to modify the *Food Guide Pyramid* to better differentiate the health benefits and risks from foods. As noted in the *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans* (2000), consumers find the *Food Guide Pyramid* to be the most useful part of the *Guidelines* and the *Guidelines* itself encourages readers to "let the pyramid guide your food choices." Yet the current *Food Guide Pyramid*, for example, groups meat, poultry, fish, dry beans, eggs, and nuts into a single "Meat and Beans Group" when research suggests that these foods may not be equivalent in terms of their health effects.

"Given the significant potential improvement in public health suggested by the current evidence, we urge you to consider revising the *Dietary Guidelines* and *Food Guide Pyramid* to emphasize the benefits of reducing foods high in *trans* fatty acids and increasing consumption of foods rich in omega-3 fatty acid.

"We would like to set up a meeting with your agencies in the next few weeks to discuss this issue. As always, the OIRA staff stands ready to assist you in these efforts."

The American Longevity and Life Extension Foundation has filed a health claim petition with FDA as a result of the OMB "Prompt Letter," saying that the disclaimer ordered by

FDA on the currently permitted health claim for omega-3 fatty acids for coronary heart disease should be reconsidered. Jonathan W. Emord, Esq. of Emord & Associates, a Washington, D.C. area law firm representing the petitioners, says the disclaimer should be removed completely to encourage making information about the relationship between omega-3 fatty acids and coronary heart disease "as widely available as possible."

The FDA's disclaimer is the second sentence in the following claim: "*Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive.*"

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## ILLINOIS BANS EPHEDRA

Gov. Rod Blagojevich approved Senate Bill 1418 on May 28, 2003 to ban the sale of Ephedra products in the State of Illinois. Introduced by Senator Barack Obama (D) of Chicago on February 20, 2003, the bill picked up steam quickly, passing in the Senate on Third Reading on March 20, when the bill arrived in the House. The Chief Sponsor was Rep. Sara Feigenholtz, D-Chicago, who was later joined by other members of both parties as co-sponsors of the bill.

The law prohibits the sale of any dietary supplement containing ephedra or ephedrine alkaloids, but exempts any product receiving the explicit approval of the Secretary of Health and Human Services as safe

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## THE NATURAL CURE NEWS

A letter from Austin A. Okwelle, publisher of *The Natural Cure News*, a newspaper in Logos, Nigeria, informs *NML* that the paper was started as “a deliberate attempt to bridge the information gap, create awareness, and stimulate interest among Nigerians about the complimentary role that natural herbs medication plays in the control of infectious diseases.”

Okwelle says that the practice of natural medicine in Nigeria is still in its infancy and very underdeveloped, making information and resource materials on the field virtually non-existent. The newspaper is published utilizing commercial printers, and it does not even own a computer system to compose the paper.

The paper uses a 12-page tabloid format that contains clinical articles by individual practitioners. For example in the 3<sup>rd</sup> issue of Volume 1, published in 2002, there is an article about Asthma: Causes, Symptoms and Herbal Cure by Dr. S.A. Olowu, M.D. of the Bulldozer Natural Health Clinic. Another article covers herbal cures for eye diseases, recommending improvement in living environments and life style for such problems as conjunctivitis. Ginseng is promoted for its invigorating properties in an article by Dr. Aladesanwa Taiwo, Director of the Marg Guinea Natural Health Centre of Ogun State, and Seth Iroko. Dr. Taiwo included another article on the effect of alcohol on health. Dr. A.A. Bello, of MD Crown Alternate Medicine Specialists, Ltd. provided another article on Alternate Approaches to Handling Strokes, in which he emphasized the use of vitamin E from edible sources.

Dr. Godwin Ihesie of Elikaf Health Services, Ltd. provided an article on Aloe Vera, describing eight different aspects of this plant for internal usage. Garlic was discussed in another article quoting Dr. Godwin Ihesie. Diets for diabetics, fruits and vegetables for healthy living were other topics covered in this issue, and finally, an interview with herbal practitioner, Chief Dr. Nze T. O Okeosisi, concluded the issue. Dr. Okeosisi urged government to integrate natural medicine into the regular schools curriculum and establish departments of natural medicine at universities. Chief Okeosisi learned herbal medicine from his father and grandfather over an eight year apprenticeship. He said since 1970, “I have not recorded any failure and no man has brought a policeman to arrest me for fraud.” He also called for a mechanism to register and certify practitioners competent be-

fore they start work.

Admitting that the tabloid is greatly affected by the paucity of funds and lack of a computer system, Okwelle asked for assistance in solving his problems. *NML* is passing on this information to readers to see if anyone has ideas or materials to contribute to the natural medicine effort in Nigeria. The Natural Cure News can be contacted by e-mail at [thenaturalcurenews@yahoo.com](mailto:thenaturalcurenews@yahoo.com) or by writing to Suite D33, Greenland Plaza, 67, Iju Road, Agege, P.O. Box 2672, Oshodi, Lagos, Nigeria.

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EPHEDRA BAN - Continued from page 17...

and effective for its intended use or any product containing ephedra that is lawfully marketed under an over-the-counter monograph approved by the U.S. Food and Drug Administration. A first violation is a Class A misdemeanor, with fines up to \$5,000 and imprisonment up to 1 year. A subsequent violation is a Class 3 felony allowing imprisonment up to 5 years and fines up to \$20,000. Class 3 felony convicts serve an average of 12 months in Illinois.

Blagojevich was the Congressman from Illinois 5<sup>th</sup> District, a state legislator and state prosecutor before becoming Governor last year, succeeding Governor James Thompson. Blagojevich was born and raised in Chicago by immigrant parents.

Obama is a graduate of Columbia and Harvard Law School and chairs the Senate Committees on Health and Human Services. He has served since 1997. Obama was born in Hawaii. Next year he is running for the U.S. Senate nomination on a platform that says the Nation has lost its way giving obscene tax cuts to the wealthy at the expense of the poor.

The State Senator teaches constitutional law at the University of Chicago and was the first African-American President of the *Harvard Law Review*. His campaign web site does not mention the ephedra legislation as one of Obama's topics of interest. In addition to the Ephedra Ban law, the only other legislation receiving the Governor's approval that was sponsored by Senator Obama is the Children's Health Insurance Program Act that was amended by the Senate and House before passage. The law extends the program and increases the eligibility requirements.

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Obama's political web site declares: "If Obama goes on to win the primary, he would have the edge over Sen. Peter G. Fitzgerald (R-Ill.). In a benchmark poll taken for Obama, when voters learn about both candidates, he leads Fitzgerald 50 percent to 31 percent."

Senator Fitzgerald's web site discloses that he has not sponsored any legislation to ban ephedra in the 108<sup>th</sup> Congress, but he has a wide array of bills with his name on them, many of them for Illinois specific projects and health issues.

### GMP FOR BOTANICALS

Twenty-one Chapters by more than 30 authors, the editors for this new volume titled: "GMP for Botanicals" Regulatory and Quality Issues on Phytomedicines" are Professor Dr. Robert Verpoorte, of the Leiden/Amsterdam Center for Drug Research, University of Leiden, The Netherlands, and Dr. Pulok K. Mukherjee, associate professor in the Department of Pharmaceutical Technology at Jadavpur University, Kolkata, India.

This book is 400 pages, \$195 US, plus \$35 for Federal Express delivery, and available from Business Horizons Pharmaceutical Publishers, of New Delhi. For more information go to [www.businesshorizons.com](http://www.businesshorizons.com) and ask about ISBN 81-9007885-2.

### QUALITY CONTROL OF HERBAL DRUGS

Just in time for regulatory specialists trying to think of ways to comply with the FDA's proposed good manufacturing practices – a new book, 816 pages, titled "Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals," has been published by Business Horizons Pharmaceutical Publishers of New Delhi. The author is Pulok K. Mukherjee, Ph.D., presently at Jadavpur University in Kolkata, India. ISBN 810900788-4-4, 1 Edition 2002. \$295 US includes delivery.

Nineteen chapters cover a wide amount of information specifically focused on botanical ingredients. Get more information on the web at [www.businesshorizons.com](http://www.businesshorizons.com) or call the U.S. distributor, Farma International in Coral Gables, FL at 305-670-4416.

### FDA REPORTS ON AGGRESSIVE ENFORCEMENT

FDA issued a 2-plus-page report on its enforcement activities on June 30, 2003 to make the point it is a much more aggressive agency now. Based on FY 1998 and FY 2002, a period of 4 years, the report states that injunctions rose from 11 to 15, recalls increased from 3532 to 5025, arrests went from 250 to 286, and convictions from 194 to 317.

Most of FDA's activities are with prescription drugs and food, so most of the warning letters and large fines are against firms that make these products. Included are fines in May 2003 against Schering Plough for violation of Good Manufacturing Practices — \$500 million, and in June 2003 against AstraZeneca for health care fraud — \$355 million and against Guidant for \$92.4 million for failing to report malfunctions of a medical device to FDA.

With regard to dietary supplements, the report states: "FDA is also committed to enhanced enforcement activities to protect the public health from unsubstantiated medical claims by dietary supplement distributors. FDA enforcement activities in this area include inspections, warning letters, seizures and injunctions, and criminal enforcement. In the past year, FDA has acted against the following categories of products: ephedrine, Coral Calcium, SARS products, and SeaSilver. The FDA is particularly vigilant regarding dietary supplements that have no proven benefits yet nonetheless make misleading claims to prevent, treat, or cure serious medical conditions, including:

- Treatments for life-threatening diseases
- Weight Loss products
- Autism treatments
- Treatments for behavioral disorders
- Treatments for SARS
- Treatments for other viral illnesses
- Treatments for mental retardation and Down's Syndrome
- Colloidal Minerals
- Supplements for smokers

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[www.NatMedLaw.com](http://www.NatMedLaw.com)

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### Supplements for drinkers

“Such claims not only cause consumers to waste their money; they also represent significant public health threats because they may deter consumers interested in protecting their health from using treatments that actually work. The FDA is also increasingly leveraging the impact of its activities through partnerships with other consumer protection and law enforcement agencies. For example, the FDA works closely with the Federal Trade Commission (FTC) under a liaison agreement that coordinates FDA’s authority over claims on product labeling and FTC’s authority over advertising claims. An ongoing collaboration between the FDA and the FTC is Operation Cure. All. Through coordination of the activities of the FDA, FTC, Health Canada, and various state Attorneys General, Operation Cure. All is an ongoing law enforcement and consumer education campaign against the fraudulent marketing of supplements and other health products on the Internet. The FDA also works with the U.S. Customs Service to ensure that certain imported goods are targeted for automatic detention.”

[www.fda.gov/oc/whitepapers/enforce.html](http://www.fda.gov/oc/whitepapers/enforce.html).

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## BETTER NUTRITION TASK FORCE COMMENTS

The Council for Responsible Nutrition (CRN) and Consumer Healthcare Products Association (CHPA) filed comments in Docket 03N-0069 on the work of an FDA Task Force on Health Information for Better Nutrition on May 27, 2003. These comments mark the beginning of a string of endorsements and ideas flowing to FDA.

CRN and CHPA addressed only one question asked by FDA – whether conventional foods and dietary supplements should be treated the same? The organizations reminded the Task Force to keep in mind that the average consumer does not know whether a particular claim for a food or dietary supplement is a health claim or a structure/function claim. FDA took the position for five years following passage of DSHEA that dietary supplements having nutritive value are also foods, independent of their status as dietary supplements, for purposes of Section 201(g)(1)(C) of the Act. Therefore, FDA allowed structure/function claims for dietary supplements having nutritive value without the statutory disclaimer and notification requirements under Section 403(r)(6) of the Act.

But FDA changed this on January 6, 2000, declaring that dietary supplements having nutritive value would have to bear the statutory disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.” FDA said this was based on a re-review of Section 201(ff) of the Act.

In February 2000, CRN and CHPA petitioned FDA to reconsider and reinstate its position prior to January 6, 2000, giving a legal rationale for doing so. They pointed out that consumer confusion would result from FDA’s new interpretation. For example, if “Calcium helps build stronger bones” is okay for a food, but now on a dietary supplement the same claim requires the statutory disclaimer to follow, consumers are not going to understand the difference.

Likewise, the antioxidant properties of vitamins C and E, which FDA acknowledges are derived from their “nutritive value,” under the Agency’s 2000 ruling would have to bear the disclaimer, while conventional food claims would not.

Therefore, CRN and CHPA said, if FDA wants to enhance consumers’ ability to make sound dietary decisions, the Agency’s January 2000 position raises serious issues of public health policy. FDA’s position requiring structure/function disclaimers for dietary supplements with nutritive value is directly at odds with the Agency’s new policy initiative on Consumer Health Information for Better Nutrition. (Dkt. No. 03N-0069, EMC 4)

In another filing on May 27, 2003, the CRN commented on four other questions on which FDA requested comments. **What body of scientific evidence should be adequate for a qualified health claim?** CRN reminded FDA that the courts have made clear there are First Amendment issues when FDA prohibits health claims that are not false and misleading but that fail to meet the NLEA standard of being supported by significant scientific agreement. Saying that the Federal Trade Commission’s standard of “adequate and reliable scientific evidence” is a relevant example of an appropriate standard that permits a wide variety of statements being made while still requiring a solid basis for claims.

FDA should consider NLEA health claims themselves,

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not the underlying nutrient/disease relationship, that must be the subject of significant scientific agreement. CRN is concerned about the “good news, bad news” format FDA has adopted for expressing qualified claims. This seems unlikely to provide consumers with a good understanding of the nature of the support that exists for the claim or FDA’s unfavorable view of the claim.

FDA should permit submission of qualified claims, rather than limiting initial submissions to unqualified claims, after which FDA will move to consider a qualified claim. FDA’s current approach is an unnecessary duplication of industry and Agency efforts.

**What types of safety concerns should be factored into FDA decision-making?** CRN said the current policy of requiring a food substance that is subject of a health claim be “lawful” is sound policy.

**What specific claims may currently be ready for consideration under the new guidance?** While CRN has not prepared a list of claims that companies may be considering, some recent reports may be of interest. B vitamins may play a role in protecting cognitive function and reducing the risk of dementia. Vitamin D plays a role, along with calcium, in reducing the risk of osteoporosis. There is evidence of a supporting role for Vitamin K. Chromium may play a role in controlling blood glucose levels in the general population or specifically in persons with diabetes. Antioxidants including vitamin C may delay the onset of cataracts, and carotenoids such as lutein may reduce the risk of macular degeneration. Magnesium plays a role in protecting against hypertension and cardiovascular disease.

Beyond vitamins and minerals, some dietary supplements that currently bear structure/function claims may be eligible for qualified health claims relating to specific disease conditions. For example, glucosamine and chondroitin sulfate may reduce the risk of arthritis, and ginger may protect against motion sickness.

**Should conventional foods and dietary supplements be treated the same or treated differently, and why?** Dietary supplements have always been a subcategory of foods under the law. Under NLEA of 1990, the law provided there could be distinct systems for regulating health claims for conventional foods and dietary supplements, but FDA decided to use the same stan-

dards and procedures for both. FDA uses the same process for evaluating qualified claims and regular health claims.

CRN said that when a health claims relates to the increased consumption of a particular nutrient or other food substance and when the substance can be provided either by a conventional food or a supplement, both should be eligible for the claim. CRN said it could see no rationale for excluding conventional foods from eligibility for qualified health claims.

But CRN said that there may be some instances where a claim will not apply equally to all products and categories of products. A general health claim for foods naturally high in soluble fiber related to reducing the risk of heart disease is based primarily on epidemiological evidence relating to high-fiber diets and not related to any one source of dietary fiber. This claim may appropriately be limited to foods. FDA has approved claims for specific soluble fibers were made available to both supplemental forms of the fiber and to conventional foods containing the fiber, provided the products meet the minimum requirements for the amount of fiber required per serving. (Dkt. No. 03N-0069, EMC 5)

The Wheat Foods Council and the American Bakers Association commented on June 30, 2003 that they support the Grocery Manufacturers of America proposal “To Establish a Premarket Notification Program for Qualified Health Claims for Food Labeling.” The two groups commended FDA for diligently assuring that the consumer is given the best nutrition information possible via health claims. (Dkt. No. 03N-0069, EMC 6)

The American Association of Retired Persons (AARP) filed seven pages of comments. In its first point, it says FDA reverses its policy of limiting the *Pearson v. Shalala* decision to dietary supplements. The Agency must follow the law requiring “significant scientific agreement.” Second, the Agency must follow the statutory procedure for approving qualified health claims, meaning through the use of the notice and comment process. The law recognizes exemptions for “authoritative statements” and interim regulations, and FDA failure to provide an opportunity for public comment undermines the statutory framework. FDA unduly relies on the FTC in allowing qualified health claims on product labels. FDA’s legal

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GMP COMMENTS -- from page 4...

or more generally by position description or departmental authorization.

Overall, Gaia wanted the GMPs rewritten to be more close to food GMPs and the proposed dietary supplement regulations in regard to the law's actual procedural requirements. They prefer knowing exactly what is expected of them as the earlier regulations spelled out. Gaia asked that the implementation period for the new GMPs be similar to the program adopted under OSHA under 29 CFR regulations. Inspections could be done at the company request to confirm compliance without penalties. This kind of implementation would help develop trust and voluntary compliance. Finally, Gaia officials asked if FDA will allow electronic signatures on batch production records, lab test results, and quality control documents since many companies are fully computerized.

Karen L. Thomas, the owner of The Korner Pharmacy, wrote May 27, 2003, that she generally agreed with the regulations, but pointed out several issues that did not seem to be covered. She expressed concern that manufacturers are not required: 1) to conduct stability testing and label products with earliest expiration dates; 2) use standard operating procedures to ensure consistent production performance; 3) test supplements for dissolution and disintegration such as is done for pharmaceutical grade products; and 4) follow manufacturing equipment cleaning and sanitation procedures.

Thomas said she was concerned that if these components were not included and the financial implications are not considered, this could have a

negative impact on the choices of supplements available. Comments 114, 116 & 117, Dkt. 96N-0417.

FDA has extended the comment period to August 11, 2003 as of May 19, 68 CFR 27008.

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### LAW SUIT AND PETITION FILED ON TRANS FAT

**B**anTransFat.com, a San Francisco, California, non-profit organization on May 1, 2003 filed a lawsuit against Kraft Foods of North America, Inc., seeking an injunction against the sale and marketing of Oreo cookies to children in California. One of the factors cited in the complaint is that Oreo cookies contain *trans* fat and this is not shown in the Nutrition Facts panel on the label. The Petition in Court was voluntarily dismissed, but the organization filed a Citizens Petition with the Food and Drug Administration dated May 22, 2003 to get FDA to move up its 2006 *trans* fat labeling proposal and to reinstate the Agency's previous proposal to reduce *trans* fat as much as possible.

The Citizens petition points out that FDA first proposed labels bear *trans* fat content on November 1, 1999, 64 FR 62746, but three years later, on November 15, 2002, 67 FR 69191, FDA proposed an amendment to place *trans* fat on a separate line with a footnote that read: "Intake of *trans* fat should be as low as possible." BanTransfat.com says that Kraft's and others response to FDA "are completely bogus and designed to prevent them from losing market share to competitors who offer *trans* fat-free products."

FDA claims it is protecting small business by delaying implementation

of the regulations to 2006. The Citizens petition says that it is unfair and violative of applicable laws and procedures for FDA to delay implementation for 2 ½ years without inviting public comments regarding the delay. It says FDA's obligation is to protect small children, not small business. The Petition predicts that from November 1999 to 2006 there will be 45,600 to 102,600 cases of coronary heart disease and 12,000 to 30,000 lives lost because of non-labeling of *trans* fat.

The Petition cites a web site, [www.fitamerica.com/famd/opages/10topfoods.asp](http://www.fitamerica.com/famd/opages/10topfoods.asp), as reporting that Kraft has refused to disclose the amount of *trans* fat in Oreo cookies on the ground that such information is "classified." What the Fit America web site actually says about Oreo cookies is:

4. Oreo Cookies: THE NUMBER ONE COOKIE IN AMERICA (6 cookies = serving size)

- Predominantly made up of 23 grams of straight-line sugar.
- Chocolate is LAST ingredient listed which means chocolate is the least of the ingredients.
- 370 empty calories with almost no nutritional benefits – you could eat 2 whole chicken breasts for the same amount of calories!
- 6 cookies have 12 grams of fat, 2.5 grams of saturated fat and 40 carbs – more than 50% of your daily carbohydrate allowance in only 6 cookies.
- Oreo cookies will set you up for craving more sugar within 3 hours.
- "Natural flavors" are manufactured chemicals to make Oreos taste like great chocolate cookies. Highly processed foods have these flavor enhancers which are nothing more than carcinogenic chemicals with no natural flavors of their own.

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**OREO COOKIES** -- from page 22...

- The Nabisco Company refused to disclose how many trans fats there are in Oreo cookies – they termed that information as ‘classified’!
- High sugar content. Sugar causes wrinkles.

Claiming that the non-profit’s lawsuit against Kraft made tens of millions of people aware of the *trans* fat issue, and that 100,000 people visited the web site from May 12 to May 22, that AOL conducted a poll in which 26% of 655,296 people said “something needs to be done,” the Citizen Petition goes on to cite references and statistics, concluding that FDA is not representing the interests of consumers. The FDA is not, the Petition charges, discharging its responsibility under Section 2(b) of the Nutrition Labeling and Education Act of 1990 to require proper labeling. The Petition is signed by Stephen L. Joseph, Chief Executive Officer of the BanTansFat.com, Inc. organization.

Kraft Foods, a division of the former Phillip Morris Companies, announced a new program to fight obesity on July 1, 2003 in response to the publicity. The Kraft initiative will consist of four parts. Among the steps Kraft is committed to taking in the four areas: **Product nutrition** - A cap on the portion size of single-serve packages; Guidelines for the nutritional characteristics of all products; A planned effort to improve existing products and provide alternative choices, where appropriate. **Marketing practices** - The elimination of all in-school marketing; Locally appropriate criteria to use with the vending; industry in different regions of the world to determine the selection of Kraft products to be sold through in-school vending machines; Guidelines for all advertising and mar-

keting practices, including advertising and marketing to children, to encourage appropriate eating behaviors and active lifestyles. **Consumer information** - Nutrition labeling in all markets worldwide, including markets where labeling is not required; Added nutrition and/or activity-related information on product labels and company websites to assist consumer choices; Guidelines for the use of health-related claims in all markets worldwide, including markets where no restrictions exist. **Advocacy and dialogue** - Advocacy for appropriate public policies to engage schools and communities in helping to improve fitness and nutrition; Increased dialogue with key stakeholders to help guide the company’s continuing response to the obesity issue.

The U.K. Food Standards Agency treats *trans* fats with some concern, but labeling is not required at this time. In a Q & A format the FSA says:

**If a food contains trans fats do they have to be mentioned in the ingredients and the nutritional information on the label?** Trans fats (also called trans fatty acids) don’t have to be included in the ingredient list of a food. However, hydrogenated fats are usually declared in the ingredient list and, since trans fats are formed during the process of hydrogenation, foods that contain hydrogenated fats will also contain trans fats.

In the nutritional information on the label, trans fats are counted as part of the total fat. But they don’t have to be listed separately, unless the label makes a claim about them, such as ‘low in trans fats’. Trans fats are not classed as saturates, monounsaturates or polyunsaturates, so they won’t be included in the figures for these. Trans fats have no known nutritional benefits and because of the effect they have on blood cholesterol, they increase the risk of coronary heart disease. Evidence suggests that the effects of trans fats are worse than saturated fats.

<http://www.foodstandards.gov.uk/healthierating/asktheexpert/fatsoils/translabel>

An update from Kraft says that it expects FDA to decide the label questions and it will comply with them. In a frequently asked questions release the company states:

**Q5. Do Oreo cookies contain trans fat?**

Like most baked goods, Oreo cookies do contain some trans fat.

A serving of our regular Oreo cookies — which is three cookies — contains 7 grams of fat, 1.5 of which is saturated fat, and 2.5 of which is trans fat.

A comparable serving of our reduced fat Oreo cookies contains 3.5 grams of fat, including 1 gram of saturated fat and 1 gram of trans fat.

While there is a difference in serving size between lawsuit allegations and updates statements from the manufacturer, the labeling controversy shows no signs of coming to an end anytime soon.

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authority justifies a different approach. The FTC itself has failed to bring a single case based on its *Enforcement Policy Statement for Food Advertising* that FDA relies upon.

AARP also said there are more effective ways to provide consumers with diet-related information to improve health than allowing qualified health claims on product labels. It is the overall diet, not specific foods that should be the focus. Nutrition information is available in newspaper, magazine, and television coverage and this provides greater opportunities than product labels and adver-

get information to consumers is to finalize the *trans* fat content labeling rule. Another is to require bold face type for calorie content of food products. (Dkt. No. 03N-0069, EMC 7)

Congressmen Henry A. Waxman, Edward J. Markey, David E. Price and Senators Barbara Boxer and Jeff Bingaman signed a four-page letter dated May 27, 2003 giving their comments to FDA. The comments were "to protest the recent 'guidance' from the Food and Drug Administration that it will lower the scientific standard for approving 'health claims' for foods," a step long sought by the food industry. "...the FDA has rejected the scientific standard required by its governing statute. This is not only a step backward for truthful, credible food labels, but an unprecedented assertion of authority on the part of the executive branch to ignore a specific congressional mandate."

NLEA requires FDA to reject health claims on food products un-

less they are supported by "significant scientific agreement." This passed unanimously in Congress. "As authors of NLEA, we strongly oppose this guidance document." The letter expressed concern with the FDA use of enforcement discretion to permanently change a statutory standard, saying it was "both a serious abuse of discretion and a precedent that could be used to undo a wide range of health and safety laws that currently protect Americans." "The FDA's decision to abandon the standard is an undeniable abdication of its statutory responsibilities. \*\*\* The reference to *Pearson* in the guidance document suggests that FDA has taken it upon itself to determine that the NLEA standard for health claims on foods violates the First Amendment. If this is the basis for the December 20 guidance document, the agency has unequivocally exceeded its authority."

The letter asked FDA to rescind the December 20, 2002 guidance as an illegal assertion of authority immediately. (Dkt. No. 03N-0069, EMC 8)

ing down practices because of high premiums for liability insurance. The Governor wants a cap on pain and suffering awards at \$250,000, no matter what kind of paraplegia the plaintiff has. Republican legislators are saying it is a vendetta against trial lawyers.

But we do not see many reports in Florida or anywhere on what is being done to reduce the 44,000 to 98,000 annual deaths caused by medical negligence.

And it is interesting to learn that President Bush is prompting HHS and USDA to change the food pyramid to prevent some of the annual 500,000 deaths from cardiovascular disease, a

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## HARVESTING HEALTH

Are consumers confused? Do they need more protection?

Protectors of the public health have got to feel good this month about all of the actions against ephedra. Taken together, the banning and suing will save up to 1,000 people from future deaths from ephedra over the next 10 years, according to some estimates of what has happened in the past 10.

Governor Jeb Bush called the Florida legislature back into special session this past week for the second time to resolve the medical malpractice crisis in which physicians are clos-

large part of which are probably caused by eating too much *trans* fat and other bad things. Good for him.

President Bush needs to push Secretary Thompson and FDA Commissioner McClellan a bit to catch up with their reading, since the FDA recently decided it would wait until 2006 to change the *trans* fat rules. This simply means, according to BanTransFat.Com that 12,000 to 30,000 more cardiovascular deaths will occur from 1999 to 2006. FDA started on its process of making a new *trans* fat rule in 1999. But, ask FDA, they say they have gotten aggressive since 1998. Maybe it is not the consumers who are confused. Could it be the policy makers?

*William J. Skinner, R.Ph.,  
Attorney at Law, Editor*