

FTC ENFORCEMENT ACTIVITIES

DIETARY SUPPLEMENT AND HEALTH FRAUD ACTIONS

DECEMBER 2002 - JULY 2003

I. FTC ENFORCEMENT ACTIONS

From December 2002 through July 2003, the Federal Trade Commission (FTC) has filed or settled 17 formal enforcement actions to combat deceptive health-related advertising, the majority involving false or unsubstantiated claims for dietary supplement products. Altogether these actions have targeted products with a total of more than \$1 billion in consumer sales. FDA staff provided technical and scientific assistance in many of the investigations leading to these actions. In specific cases, as noted below, the FDA also conducted seizure actions concurrently with FTC enforcement. A complete report of FDA's enforcement efforts since December 2002 is described in FDA's Dietary Supplement Enforcement Report June 2003, available on the agency's web site at www.fda.gov.

July 2003

Wellquest International, Inc. et al. (Civil Action Nos. not yet available)

- Products:** "Bloussant" and "EnerX" herbal supplements and "D-Snore" spray.
- Claims:** "Bloussant" increases breast size; "EnerX" with yohimbine treats erectile dysfunction and is safe with no side effects; "D-Snore" reduces or eliminates snoring.
- Status:** Complaint and final stipulated orders including \$3.2 million in consumer redress to be filed in the U.S. District Court for the Central District of California, Western Division on July 10, 2003.

Lifestyle Fascination (Civil Action No. not yet available)

- Products:** "Beverly Hills Spa Diet," "FTF" liquid chitosan supplement, "Carni Q-Gel" heart supplement, and "Sani-Mate Plug-In Sterilizer" (air cleaner).
- Claims:** Beverly Hills Diet causes weight loss of 10 lbs. in 1 weekend; FTF chitosan causes weight loss without giving up favorite fatty foods and lowers cholesterol; Carni Q-Gel is recommended by cardiologists for heart health and for patients with angina or arrhythmia; Sani-Mate air cleaner reduces airborne bacteria and reduces incidence of disease or infection.
- Status:** Complaint and Modified Consent Decree filed in U.S. District Court for the District of New Jersey on July 9, 2003; injunction and civil penalty of \$175,000.

Health Labs of North America et al. (Civil Action No. 03 1457)

- Product:** "Berry Trim Plus" supplement with ephedra and hydroxycitric acid (HCA).
- Claims:** Causes rapid and substantial weight loss without diet or exercise; safe.
- Status:** Complaint and stipulated final order filed in the U.S. District Court for the District of Columbia on July 1, 2003.

USA Pharmacal Sales, Inc. et al. (Civil Action No. 8:03-CV-1366-T-23EAJ)

- Products:** Multiple supplement products such as “Meta-Biological,” “Fat-Sponge in a Pill,” “Calotrol/MD,” and “Virile V.” Ingredients include ephedra, chitosan, glucomannan, HCA, chromium picolinate, yohimbine, and androstenedione.
- Claims:** Causes rapid, substantial and permanent weight loss; treats erectile dysfunction; safe (ephedra/yohimbine/androstenedione products only).
- Status:** Complaint and stipulated final order filed in the U.S. District Court for the Middle District of Florida, Tampa Division on July 1, 2003.

June 2003

Michael S. Levey et al. (Civil Action No. CV-02-4670 GAF (AJWx))

- Products:** “Zymax” and “MillenexES” ephedra supplements; “Serotril” St. John’s wort supplement; and “Cartazyne DS” glucosamine and chondroitin supplement.
- Claims:** Ephedra and St. John’s wort supplements cause substantial weight loss with no diet or exercise; ephedra products cause no side effects. Glucosamine/chondroitin supplement cures arthritis, rebuilds cartilage and is alternative to joint replacement.
- Status:** Complaint, including charges that defendant Levey violated a 1993 FTC order, filed in U.S. District Court, Central District of California on June 30, 2003.

Seasilver USA, Inc. et al. (Civil Action No. CV-S-03-0676-RLH-LRL)

- Product:** “Seasilver” multi-vitamin/mineral/amino acid supplement with aloe vera, phyto-silver, herb Pau D’Arco, sea vegetables, and cranberry concentrate.
- Claims:** Treats or cures cancer, AIDS, diabetes, and 650 other diseases; safe.
- Status:** Complaint filed in U.S. District Court for the District of Nevada on June 12, 2003; Defendants under restraining order, receivership, and asset freeze.
- FDA Action:** Concurrent FDA seizure actions on June 14 and June 25, 2003. See FDA Dietary Supplement Report June 2003.

Kevin Trudeau; Robert Barefoot et al. (Civ. Action Nos. 98 C 0168; 03 C 904)

- Products:** “Coral Calcium Supreme” supplement and “Biotape” adhesive strips.
- Claims:** Coral calcium treats or cures cancer, multiple sclerosis, heart disease and other serious diseases; Biotape relieves severe pain from arthritis, sciatica, migraines.
- Status:** Complaints filed in U.S. District Court for the Northern District of Illinois, Eastern Division, on June 9, 2003; Defendants under preliminary restraining order and asset restriction.
- FDA Action:** Concurrent FDA seizure action on June 19, 2003. See FDA Dietary Supplement Report June 2003.

Unither Pharma, Inc. et al. (FTC File No. 022 3036)

- Product:** “HeartBar” food bar and powder with amino acid L-Arginine.
- Claims:** Reduces risk of heart disease, reverses heart damage, reduces or eliminates need for surgery and medications; decreases angina pain by 70% and leg pain by 66%.
- Status:** Consent agreement; public comment period closes July 14, 2003.

QT, Inc.; Q-Ray, Company, Bio-Metal, Inc. et al. (Civil Action No. 03 C-3578)

- Products:** “Q-Ray” ionized metal bracelet.
- Claims:** Relieves pain from musculoskeletal conditions, sciatica, headaches, tendinitis, injuries and other causes.
- Status:** Complaint filed in U.S. District Court for the Northern District of Illinois, Eastern Division on May 27, 2003. Defendants under preliminary restraining order and asset freeze.

MAY 2003

A. Glenn Braswell; Gero Vita Int’l, Inc. et al. (Civil Action No. CV-03-3700 DT (PJWx))

- Products:** Various Gero Vita and Theraceutical brand supplements.
- Claims:** “Lung Support Formula” cures or treats asthma, emphysema and other respiratory problems; “Antibetic Pancreas Tonic” cures or treats Type I and Type II diabetes; “GH3,” “Theraceuticals GH3 Romanian Youth Formula” reverses and prevents Alzheimer’s disease and dementia and increases lifespan; “Chitoplex” causes weight loss without diet or exercise; “Testorex” treats erectile dysfunction in 62% to 95% of men.
- Status:** Complaint filed in U.S. District Court for the Central District of California, Western Division on May 27, 2003.
- FDA Action:** FDA staff provided technical and scientific support in development of FTC case. See FDA Dietary Supplement Report June 2003.

APRIL 2003

Snore Formula, Inc. et al. (FTC File No. 022-3247)

- Product:** “Dr. Harris Original Snore Formula” herbal supplement tablets.
- Claims:** Prevents sleep apnea in adults and children, reduces or eliminates snoring.
- Status:** Consent agreement; public comment period closed May 15, 2003.

ValueVision International, Inc. (Civil Action No. 03-2890)

- Product:** “Physician’s RX” dietary supplement with vitamins, minerals, antioxidants.
- Claims:** Reduces fatigue associated with prescription drugs and various illness; increases energy, stamina, endurance; relieves arthritis symptoms.
- Status:** \$215,000 civil penalty consent decree, in connection with violation of a 2001 FTC order, entered April 17, 2003.

FEBRUARY 2003

CSCT, Inc. et al. (Civil Action No. 03 C 00880)

- Product:** “Zoetron” machine electromagnetic therapy device.
- Claims:** Kills cancer cells; cures cancer.
- Status:** Complaint filed in U.S. District Court for the Northern District of Illinois on February 6, 2003.

JANUARY 2003

Slim Down Solution, LLC et al. (Civil Action No. 03-80051-CIV-PAINE)

- Product:** “Slim Down Solution” supplement with D-glucosamine.
- Claims:** Causes significant weight loss without diet or exercise.
- Status:** Complaint and stipulated preliminary injunction filed in U.S. District Court for the Southern District of Florida on January 22, 2003.

Dr. Clark Research Association, et al. (Civil Action No. 1:03CV0054)

- Product:** “Complete Herbal Parasite Program” and “Dr. Clark’s New 21 Day Program for Advanced Cancers” herbal supplements and “Zapper” electrical devices.
- Claims:** Cure AIDS, advanced and terminal cancers, other serious diseases.
- Status:** Complaint filed in U.S. District Court for Northern District of Ohio on January 8, 2003.

DECEMBER 2002

Vital Dynamics, Inc.; J. Michael Ernst et al. (Civil Action No. 03-437RSWL(SHSx))

Settlement

- Product:** “Isis System” dietary supplement and topical cream.
- Claims:** Significantly increases breast size; safe.
- Status:** Complaint and stipulated final order filed in U.S. District Court for the Central District of California, Western Div. on January 16, 2003.

Mark Nutritionals, Inc. et al. (Civil Action No. SA02CA1151EP)

- Product:** “Body Solutions Evening Weight Loss Formula” supplement.
- Claims:** Causes substantial and permanent or long-term weight loss without diet or exercise.
- Status:** Stipulated order for preliminary injunction with asset freeze entered against two individual defendants on December 23, 2002 in U.S. District Court for the Western District of Texas, San Antonio Div.

II. FTC E-MAIL ADVISORIES

In addition to the formal enforcement actions listed above, the Federal Trade Commission continues to combat health fraud on the Internet through “Operation Cure.All” and other initiatives. Since December 2002, the Federal Trade Commission has issued e-mail advisories to approximately 163 web site operators and e-mail solicitors making fraudulent claims in the promotion of dietary supplements and other health-related products as described below. The Food and Drug Administration has been a principal partner in these efforts, working with the FTC to identify fraudulent sites and issuing warning letters. A complete description of FDA’s warning letters and other activities related to Internet health fraud is described in FDA’s Dietary Supplement Enforcement Report June 2003, available on the agency’s web site at www.fda.gov.

JUNE 2003

Coral Calcium Warning Letters

- Products:** Coral calcium supplements.
- Claims:** Cures or treats variety of serious diseases.
- Status:** FTC sent e-mail warning letters to 34 web site operators making allegedly false or unsubstantiated claims for coral calcium supplements, in conjunction with June enforcement action against Kevin Trudeau, Robert Barefoot, and others (see above). FTC staff is assessing revised web sites and working with these marketers to come into compliance.
- FDA Action:** FDA concurrently issued warning letters to 18 firms operating 24 web sites that market coral calcium products. *See* FDA Dietary Supplement Report June 2003.

MAY 2003

SARS Warning Letters

- Products:** A variety of dietary supplements, personal air purifiers, respirator masks, gloves, disinfectant wipes and sprays.
- Claims:** Prevents, treats or even cures Sever Acute Respiratory Syndrome (SARS).
- Status:** FTC sent e-mail warning letters to 48 web site operators and 7 e-mail solicitors for allegedly false or deceptive SARS-related marketing. FTC staff is assessing revised sites and working with these marketers to bring sites into compliance.
- FDA Action:** FDA concurrently issued warning letters to 8 firms promoting SARS products on the Internet. *See FDA Dietary Supplement Report June 2003.*

APRIL 2003

Biological/Chemical/Nuclear Terrorism Protection Warning Letters

- Products:** A variety of dietary supplements and devices.
- Claims:** Protects, treats or cures ailments associated with biological, chemical, or nuclear agents.
- Status:** Following its 2001 and 2002 efforts to crack down on bogus terrorism defense products, the FTC sent e-mail warnings to an additional 39 web sites promoting products to protect against anthrax, smallpox, and various chemical and nuclear agents.

MARCH 2003

Potassium Iodide Warning Letters

- Products:** Potassium iodide and potassium iodate products.
- Claims:** For protection against “dirty bombs,” nuclear terrorism and other nuclear emergencies.
- Status:** FTC sent e-mail warning letters to 35 web sites making exaggerated claims about the protective effects of potassium iodide for nuclear emergencies. FTC staff is assessing revised sites and working with these marketers to bring sites into compliance.