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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**STATEMENT OF**  
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**FOOD AND DRUG ADMINISTRATION**  
**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE**  
**COMMITTEE ON GOVERNMENT REFORM**  
**HOUSE OF REPRESENTATIVES**

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**FOR RELEASE ONLY UPON DELIVERY**

## **INTRODUCTION**

Thank you, Mr. Chairman for this opportunity to testify before your Committee at this hearing entitled, “The Regulation of Dietary Supplements: A Review of Consumer Safeguards.”

## **BACKGROUND ON REGULATION OF DIETARY SUPPLEMENTS**

Many Americans take some type of dietary supplement, and in some cases, there is evidence that these vitamins and minerals and other products could offer important health benefits. The Dietary Supplement Health and Education Act (DSHEA) of 1994 (P.L. 103-417) amended the Federal Food, Drug, and Cosmetic (FD&C) Act to set up a distinct regulatory framework for these products. DSHEA is intended to strike the right balance between providing consumers access to safe dietary supplements that they may choose to help maintain and improve their health, and giving the Food and Drug Administration (FDA or the Agency) regulatory authority to take action against supplements and supplement ingredients that present safety problems, have false or misleading claims, or are otherwise adulterated or misbranded. DSHEA and FDA’s implementing regulations establish special requirements for dietary supplements that differ in some respects from those covering “conventional” foods.

DSHEA defined the term “dietary supplement” as a product that, among other things, is intended for ingestion, is intended to supplement the diet, is labeled as a dietary supplement, is not represented as a conventional food or as a sole item of a meal or diet,

and contains one or more “dietary ingredients.” “Dietary ingredients” are defined as vitamins, minerals, amino acids, herbs or other botanicals, dietary substances (such as enzymes), and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Dietary supplements may be found in many forms, such as tablets, capsules, powder, liquids, or bars.

## **LABELING OF DIETARY SUPPLEMENTS**

Under the FD&C Act and FDA’s implementing regulations, the label of a dietary supplement must bear a statement of identity (product name) that identifies the product as a dietary supplement (Title 21 United States Code [U.S.C.] §321 [ff][2][C] and §342 [s][2][B] and Title 21 Code of Federal Regulations [CFR] §101.3 [g]); nutrition information in the form of a Supplement Facts panel (21 U.S.C. [Q][5][F] and 343 [s][2][A] and 21 CFR §101.36 and §101.4 [h]); a list of any ingredients not listed in the Supplement Facts panel (21 U.S.C. §343 [i][2] and 21 CFR §101.4 [g]); the name and address of the manufacturer, packager, or distributor (21 U.S.C. §343 [e][1] and 21 CFR §101.5); and the net quantity of contents (21 U.S.C. §343 [e][2] and 21 CFR §101.105).

In addition, if the labeling includes a claim relating to an effect on the structure or function of the body, a claim of general well-being, or a claim of a benefit related to a classical nutrient deficiency disease, the product must bear a disclaimer stating that FDA has not evaluated the claim and that the product is not intended to diagnose, treat, cure, or prevent any disease. Furthermore, a manufacturer of a dietary supplement making such a health claim must have substantiation that the claim is truthful and not misleading and

must notify FDA that its product bears such a claim within 30 days of marketing the product with the claim.

## **DIETARY SUPPLEMENT SAFETY**

### **Statutory Framework**

As with most foods, there is no requirement for manufacturers of most dietary supplements to provide evidence of product safety to FDA prior to marketing. Accordingly, FDA regulates the safety of dietary supplements primarily through a post-market evaluation of whether the product is adulterated under one of the provisions of the FD&C Act. The burden of proving lack of safety rests with the Federal government. There is a 75-day pre-market notification requirement for dietary supplements that contain certain dietary ingredients that were not marketed in the United States before October 15, 1994, or “new dietary ingredients.” Specifically, the manufacturer or distributor of a supplement that contains one or more new dietary ingredients must submit a pre-market notification to FDA unless all new dietary ingredients in the product have been present without chemical alteration in the food supplement as articles used for food. In its notification to FDA, the manufacturer or distributor of the supplement must submit information, including citation to published articles, that forms the basis for the firm’s conclusion that the dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. Unless there is a history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe

when used as recommended or suggested in the labeling of the dietary supplement, the supplement is deemed adulterated.

## **ENFORCEMENT ACTIONS**

At the core of FDA’s DSHEA enforcement efforts is our commitment to work with industry in order to encourage the legitimate manufacture, sale, and use of dietary supplements while enforcing the law aggressively against fraudulent product claims and other illegal practices. Dietary supplement enforcement efforts include inspections that have resulted in voluntary compliance, voluntary recalls, warning letters, seizures and injunctions, criminal enforcement, and joint enforcement actions with the Federal Trade Commission (FTC) and the Department of Justice.

FDA shares Federal oversight of dietary supplements with FTC. FDA regulates the safety, manufacturing, and labeling of dietary supplements, while FTC has primary responsibility for regulating the advertising of these products. Over the last few years, FDA and FTC have worked together to ensure that there is a seamless assertion of our jurisdiction over these products. With the mutual goal of consumer protection, FDA and FTC chair an interagency health fraud steering committee that includes Federal agencies in the U.S., Canada, and Mexico. Also, as part of FDA’s effort to curb Internet health fraud, the Agency has conducted several “surfs” to identify fraudulent marketing of health care products over the Internet. These actions were carried out in partnership with FTC and other law enforcement and public health authorities in the U.S. and abroad.

FDA works closely with the Drug Enforcement Administration (DEA) when illegal steroid products are marketed as dietary supplements. The Anabolic Steroid Control Act (ASCA) of 2004 classified androstenedione (an anabolic steroid precursor) and a number of other steroid substances as controlled substances by defining them as anabolic steroids, which fall under Schedule III of the Controlled Substances Act. The new law provided for scheduling of new steroid substances not covered by the ASCA through DEA's administrative scheduling process.

When criminal sanctions may be warranted, FDA's Office of Criminal Investigations (OCI) gets involved. OCI is the entity within the Agency responsible for the conduct and coordination of criminal investigations and, as such, maintains liaison and cooperative investigative efforts with other Federal, state, local, and international law enforcement agencies. OCI is instrumental in implementing FDA criminal investigation policy, training, and coordination. OCI uses all customary and legal criminal investigative techniques, interfaces directly with Federal and local prosecutorial offices, and participates in grand jury proceedings and judicial actions as required.

From October 2002 through February 2006, FDA has conducted 588 domestic inspections of dietary supplement manufacturers, issued more than 350 "warning letters" and "cyber letters" to marketers of dietary supplement products, seized products worth more than \$13.4 million, supervised the voluntary destruction of more than \$3 million worth of products marketed as dietary supplements that were promoted with unsubstantiated claims or that were unapproved drugs or were unsafe, and obtained

permanent injunctions against five firms distributing misbranded or unapproved drugs as dietary supplements.

FDA enforcement has extended to our nation's borders, where we have refused importation for more than 4,000 foreign shipments of potentially unsafe or misbranded dietary supplements offered for entry in the U.S. The Agency's enforcement actions send a clear message that FDA will not tolerate fraudulent practices that victimize and endanger consumers.

As with all of FDA's activities, priorities are established based upon the direct impact upon public health. Products that present a direct health hazard to consumers are the Agency's highest priority, although FDA also proceeds against products that present indirect health threats. When the Agency encounters such products, FDA will use all available civil and administrative remedies to assure that the product is quickly removed from the market. We also aggressively publicize our actions to warn consumers and health professionals about such products. In some cases, the Agency may initiate a criminal prosecution against manufacturers or distributors of violative products.

FDA recognizes that traditional enforcement actions and coordinated efforts with other agencies are necessary, but these steps are not the only components of a thoughtful enforcement strategy. We fully appreciate that the dietary supplement industry has a vested interest in curbing fraudulent operators and practices, and that most of FDA's regulated industries are interested in complying with the FD&C Act, and do so. For this

reason, FDA will continue to assist the industry by issuing regulations and guidance documents addressing the manufacture, labeling, and sale of dietary supplements and other FDA-regulated products.

## **SCIENTIFIC RESEARCH**

In order to be informed about the safety of dietary supplements, in addition to assessing known reported adverse events, FDA evaluates published literature, evidence-based reports, and the known pharmacology of a compound in order to assist in the evaluation of dietary supplement products. Collaboration with academic centers such as the National Center for Natural Products Research (NCNPR), Federal partners such as the National Institutes of Health and the National Center for Toxicological Research (NCTR), and our consumer and industry stakeholders are important in our efforts to develop a comprehensive safety evaluation of dietary supplement products. For example, the partnership that FDA has with NCNPR at the University of Mississippi is valuable for finding practical solutions to scientific problems encountered with botanical dietary ingredients. For example, in the case of Citrus aurantium extract, FDA needed to ascertain how much synephrine is typically present in imported and domestic Citrus aurantium extracts. To answer this question, scientists at the University of Mississippi obtained citrus plant materials and citrus extracts from a variety of sources and measured the amount of synephrine contained in each sample. A comparison of the amount of synephrine extracted from raw citrus plant materials and the marketed Citrus aurantium extracts revealed that Citrus aurantium extracts typically contain up to 4 percent synephrine. However, Citrus aurantium extracts containing 90 percent synephrine



contain an added amount of chemical synephrine. This allowed FDA to monitor the safety of dietary supplements containing Citrus aurantium and provided a standardized test article for a collaborative project with NCTR to study the effects of Citrus aurantium extract on developmental and reproduction parameters in the rat. For dietary supplements containing botanical ingredients, the development of a toxicologic science base can be especially difficult because of the complex mixture of chemicals contained in botanical extracts. In the case of dietary supplement products containing Citrus aurantium extract, there are a variety of naturally occurring chemicals such as tyramine and octopamine, which can have a pharmacological effect on blood pressure and heart rate. Depending on the harvest time and agricultural growing conditions of the citrus plant, the amount of each chemical extracted can vary from one product to another. It is critical that FDA continue to base its conclusions on evidence-based scientific information. We are continuing to work with our colleagues at NCTR and our partners at NCNPR at the University of Mississippi to develop a strong science base on which to support our regulatory actions.

### **CFSAN ADVERSE EVENT REPORTING SYSTEM (CAERS)**

FDA's Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS) monitors adverse event reports for CFSAN-regulated products, i.e. food (including dietary supplements) and cosmetics. Adverse event reporting for dietary supplements is not mandatory. CAERS is a computerized system that records reports submitted voluntarily by industry, health care providers, and consumers. Since becoming operational in June 2003, CAERS has received approximately 1,145 adverse

event reports. Using CAERS, CFSAN staff can track, do preliminary evaluations, and monitor adverse event reports and consumer complaints received about CFSAN-regulated products. Individual serious adverse event reports are reviewed by appropriately assigned CFSAN staff within days of receipt. Adverse event reports are reviewed on a regular basis by the program offices responsible for a given product category. FDA also notifies the manufacturer (when the manufacturer is identified) when it receives an adverse event report about a CFSAN-regulated product. Efforts are on-going to incorporate a thesaurus of botanically-derived ingredients used in dietary supplements into the CAERS database to enable more sophisticated search strategies and to create a thesaurus for cosmetic ingredients. Work will be done to ensure compatibility of the system with Federal Health Architecture Initiatives regarding post-marketing surveillance and public health information.

## **DIETARY SUPPLEMENT GOOD MANUFACTURING PRACTICES**

Under DSHEA, another important tool of FDA's regulatory and surveillance activities to help ensure the safety of dietary supplement products is the Agency's authority to promulgate regulations for dietary supplement current good manufacturing practices (cGMPs). Such regulations will help ensure product quality and consistency. This regulation is under review at the Office of Management and Budget. FDA will continue to take action against dietary supplement products that threaten the public health and believe that the new cGMP regulations will provide another level of safety for the American public. Currently, dietary supplement manufacturers are subject to the

requirements specified in Title 21, CFR, part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.

## **CONSUMER HEALTH INFORMATION FOR BETTER NUTRITION INITIATIVE**

As part of FDA's efforts on dietary supplements, the Agency has been working to inform consumers about these products and their uses through the Consumer Health Information for Better Nutrition Initiative. The focus of this effort is to make available more scientifically accurate information about foods and dietary supplements so Americans know the health consequences of what they consume. This Better Health initiative is designed to foster two complementary goals concerning the labeling of food and dietary supplements:

- encouraging marketers of conventional foods and dietary supplements to make accurate, science-based claims about the health benefits of their products, and
- bringing enforcement actions against those who make false or misleading claims.

As a part of this initiative, FDA has undertaken numerous enforcement actions against dietary supplement manufacturers and others who make false or misleading claims about the health benefits or other effects of their products. I have included as an addendum to this statement some examples of recent enforcement actions.

Mr. Chairman, thank you for this opportunity to describe FDA's regulatory program for dietary supplements. I would be pleased to answer any questions.

## **ADDENDUM**

### **Dietary Supplement Actions – June 2004 – March 2006**

#### **June 2004**

##### **Prison Sentence for Selling Laetrile as a Cure for Cancer**

A U.S. District Court judge in the Eastern District of New York sentenced defendant Jason Vale to 63 months in prison and 3 years of supervised release. Vale, through Christian Bros., had sold Laetrile over the Internet as a cure for cancer and saturated the public with a massive Internet and “spam” E-mailing marketing campaign which guaranteed persons a cancer free life if they used his products.

*<http://www.fda.gov/bbs/topics/news/2004/NEW01080.html>*

#### **July 2004**

##### **Metabolife Indicted for Making False Representations to FDA**

A Grand Jury in the Southern District of California returned an indictment against Metabolife International, Inc., and its founder, Michael J. Ellis. The indictment charges both defendants with making false, fictitious, and fraudulent representations to FDA and two counts of corruptly endeavoring to influence, obstruct, and impede proceedings concerning the regulation of dietary supplements containing ephedra being conducted by FDA. Until FDA banned the use of ephedrine alkaloids in dietary supplements, Metabolife was one of the largest retailers of dietary supplements in the United States,

based largely on sales of its ephedra-based product. Metabolife and Ellis are charged with falsely representing a number of different material facts to FDA in letters to the Agency, including statements indicating that the firm had not received any adverse health reports about its product.

[www.fda.gov/bbs/topics/news/2004/doj72204.html](http://www.fda.gov/bbs/topics/news/2004/doj72204.html)

### **U.S. District Judge Issues Permanent Injunction Against Lane Labs-USA, Inc.**

A judge in the United States District Court for the District of New Jersey, found that three products sold by Lane Labs-USA, Inc. and its president Andrew J. Lane (the defendants) as dietary supplements and a cosmetic - Benefin, MGN-3 and SkinAnswer – are unapproved new drugs under Federal law because they were being marketed as treatments for cancer, HIV, and skin cancer without FDA approval. In addition, the judge permanently enjoined the defendants from distributing the products unless the products are first either approved for marketing by FDA or distributed pursuant to an investigational new drug (IND) application for purposes of conducting a clinical trial. The judge also ordered the defendants to pay restitution to all purchasers of the products since September 22, 1999. Lane Labs appealed the decision to allow restitution. In October 2005, the U.S. Court of Appeals for the Third Circuit ruled in FDA’s favor, affirming the District Court’s decision regarding restitution.

<http://www.fda.gov/bbs/topics/news/2004/NEW01086.html>

## **August 2004**

### **Firms Voluntarily Destroy Over \$287,000 Inventory of Ephedra**

In August 2004, two companies voluntarily destroyed dietary supplements containing ephedrine alkaloids. IDS Sports, Oveida, Florida, voluntarily destroyed approximately \$230,315.16 worth of dietary supplement products. Europa Sports Products, Inc., Mesquite, Texas, voluntarily destroyed 19 pallets containing 1,341 cases of a liquid products containing ephedra (ephedrine alkaloids), worth \$28,988.00, and 1,142 cases of sport drinks containing ephedrine alkaloids worth approximately \$28,000.

### **Warning Letter to Manufacturer of Cortislim**

FDA and the Federal Trade Commission cooperated in an action to address claims made by Window Rock Enterprises in its labeling and promotion of the product Cortislim, a product promoted heavily through infomercials for weight loss. In August 2004, FDA issued a Warning Letter to Window Rock Enterprises. The Warning Letter stated that Cortislim is misbranded because the product's labeling includes unsubstantiated claims relating to weight loss. In September 2004, FTC filed a Stipulated Interim Agreement and Order against Window Rock and several of the firm's management. In the agreement, the firm agreed to cease all promotion of products for serious diseases or weight loss if such representations were not supported by competent and reliable scientific evidence that substantiated the claims.

*<http://www.ftc.gov/opa/2004/10/windowrock.htm>*

## **October 2004**

### **Warning Letters issued for Unsubstantiated Weight Loss Claims**

FDA issued Warning Letters to nine firms that were marketing dietary supplement products with claims regarding weight loss. Many of the claims were related to the products' purported ability to block the absorption of fats or carbohydrates. FDA found that the products were misbranded because the claims were not supported by competent and reliable scientific evidence.

*<http://www.cfsan.fda.gov/~dms/wl-list2.html>*

## **November 2004**

### **Seizure of Products that Contain Ephedrine Alkaloids**

The U.S. Marshals Service, in a case initiated by FDA, seized more than 2.1 million capsules of Vitera-XT in the possession of Asia MedLabs, Houston Texas. Although the product was labeled as a "traditional Asian herbal formulation," the product is still considered a dietary supplement because its label included a "Supplement Facts" panel and the dietary supplement disclaimer. FDA initiated the seizure because the product contains ephedrine alkaloids. The firm's Internet website also made claims that the product treats diseases or conditions.

*<http://www.fda.gov/bbs/topics/news/2004/NEW01140.html>*

## **December 2004**

### **Seizure of ginseng found to contain illegal pesticides**

The U.S. Marshals, in a case initiated by FDA, seized ginseng products from FCC Products, Inc., Livingston, New Jersey. FDA initiated the action because the ginseng products are considered adulterated under the Federal Food, Drug, and Cosmetic Act because they contain unsafe chemical residues from the pesticides procymidone and quintozone. These residues are deemed unsafe because there has been no maximum amount of residues allowed (tolerance) established for them in ginseng. FDA is responsible for enforcing pesticide tolerances and food additive regulations.

*[http://www.fda.gov/fdac/departs/2005/205\\_upd.html#ginseng](http://www.fda.gov/fdac/departs/2005/205_upd.html#ginseng)*

## **November 2005**

### **FDA and FTC Joint Action Against Marketers of Unapproved Alternatives to Hormone Therapies**

In November 2005, FDA and the Federal Trade Commission joined to take action against a number of products that are promoted for use as alternatives to hormone therapies and that claim to prevent, treat, cure, or mitigate serious diseases. FDA issued “Warning Letters” to 16 dietary supplement or hormone cream manufacturers who claim their products are effective in preventing or treating diseases and conditions such as cancer, heart disease, and osteoporosis. The alternative therapies are often promoted as “natural” or “safer” treatments that can be used in place of approved hormone therapies. FTC issued letters to 34 websites, stating that FTC is unaware of any competent and



reliable scientific evidence to support the claims.

[www.fda.gov/bbs/topics/NEWS/2005/NEW01260.html](http://www.fda.gov/bbs/topics/NEWS/2005/NEW01260.html)

## **December 2005**

### **Seizure of Dietary Supplements Containing Ephedrine Alkaloids**

In December 2005, the U.S. Marshals, at the request of FDA, seized Nature's Treat Energy Plus #1, a dietary supplement found to contain ephedrine alkaloids. The product was seized in both Gainesville, Texas, at Nature's Treat, Inc., and in Eugene, Oregon, at ACD Distributing, LLC. Marshals seized 2634 bottles from the Texas location and 363 bottles from the Oregon location. The seized products had a total retail value of approximately \$150,000.

[www.fda.gov/bbs/topics/NEWS/2005/NEW01267.html](http://www.fda.gov/bbs/topics/NEWS/2005/NEW01267.html)

### **Actions to Address Fraudulent Avian Flu Therapies**

In December 2005, FDA issued "Warning Letters" to nine companies marketing bogus products with claims that the products would prevent, cure, or treat avian flu or other forms of influenza. FDA is not aware of any scientific evidence that the products would be safe or effective for treating or preventing avian flu. Eight of the letters were issued to firms marketing dietary supplements, and the other letter was issued to a firm marketing a drug product. Examples of the claims cited include, "prevents avian flu," "a natural virus shield," and "kills the virus."

[www.fda.gov/bbs/topics/NEWS/2005/NEW01274.html](http://www.fda.gov/bbs/topics/NEWS/2005/NEW01274.html)

## **January 2006**

### **Seizure of Dietary Supplements Containing Ephedrine Alkaloids**

In January 2006, the U.S. Marshals, at the request of FDA, seized dietary supplements that contain ephedrine alkaloids from ATF Fitness Products, Oakmont, Pennsylvania. The seized products include five boxes of dietary supplements, worth approximately \$16,000.

*[www.fda.gov/bbs/topics/NEWS/2006/NEW01297.html](http://www.fda.gov/bbs/topics/NEWS/2006/NEW01297.html)*

## **February 2006**

### **Seizure of Dietary Supplement with Ephedrine Alkaloids**

In February 2006, the U.S. Marshals, at the request of FDA, seized approximately \$3 million worth of dietary supplements and raw materials that were labeled to contain ephedrine alkaloids at Hi-Tech Pharmaceuticals, Norcross, Georgia. The seizure included more than 200 cases of finished products, more than 200 boxes of bulk tablets, and nine of ephedrine alkaloid raw materials.

*[www.fda.gov/bbs/topics/NEWS/2006/NEW01325.html](http://www.fda.gov/bbs/topics/NEWS/2006/NEW01325.html)*