



STATEMENT OF
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INTRODUCTION

Thank you, Mr. Chairman for this opportunity to testify before your Subcommittee at this hearing entitled, “Ten Years After the Implementation of DSHEA: The Status of Dietary Supplements in the United States.”

BACKGROUND ON REGULATION OF DIETARY SUPPLEMENTS

Many Americans take some type of dietary supplement, and in many cases, there is either strong or suggestive evidence that many of these vitamins and minerals and other naturally occurring products have important health benefits. The Dietary Supplement Health and Education Act of 1994 (DSHEA) (P.L. 103-417) amended the Federal Food, Drug, and Cosmetic (FD&C) Act to set up a distinct regulatory framework for these products in an attempt to strike the right balance between providing consumers access to dietary supplements that they may choose to use to help maintain and improve their health, and giving the Food and Drug Administration (FDA or the Agency) regulatory authorities to take action against supplements or supplement ingredients that present safety problems, have false or misleading claims, or are otherwise adulterated or misbranded. Although dietary supplements are regulated as foods, in that pre-market approval is not mandatory, DSHEA and FDA’s implementing regulations establish special requirements for dietary supplements that differ in some respects from those covering “conventional” foods, and that also differ from those that apply to drug products (prescription and over-the-counter).

Congress 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 a “dietary ingredient.” “Dietary ingredients” are defined as vitamins, minerals, amino acid, 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, 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; nutrition information in the form of a Supplement Facts panel; a list of any ingredients not listed in the Supplement Facts panel; the name and address of the manufacturer, packager, or distributor; and the net quantity of contents. In addition, if the labeling includes a claim to affect 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 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. However, there is a 75-day pre-market notification requirement for manufacturers or distributors of dietary supplements that contain “new dietary ingredients” that were not marketed in the U.S. before October 15, 1994, unless the supplement contains only ingredients that have been present without chemical alteration in the food supply as an article used for food. There must be a history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe when used as recommended in the labeling of the supplement. 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 concluding that the dietary supplement containing the new dietary ingredient will reasonably be expected to be safe.

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, and our consumer and industry stakeholders is important in developing a comprehensive safety evaluation of dietary supplement products. For example, the partnership that FDA has with NCNPR at the University of Mississippi is valuable in order to find practical solutions to practical scientific problems. For dietary supplements containing botanical ingredients, development of such a science-base can be especially difficult because of several unique factors, such as the complexity of the chemicals that make up these products and the variability between one product and another.

CFSAN Adverse Event Reporting System (CAERS)

Adverse event reports (AERs) are an important tool for developing a “signal” which can help FDA to identify potential safety problems with dietary supplements. Last year, FDA’s Center for Food Safety and Applied Nutrition (CFSAN) put in place the CFSAN Adverse Event Reporting System (CAERS) to monitor adverse event reports on CFSAN-regulated products, i.e. food (including dietary supplements) and cosmetics. Adverse event reporting for dietary supplements is not mandatory and consists of voluntary reporting from industry, health care providers, and consumers. CAERS is a computerized system that records voluntarily received reports and separates them into product problems and adverse events. This system started collecting reports after June 15, 2003, and unifies CFSAN’s adverse event reporting through one common portal. Future planned capabilities include transitioning data from older systems into the CAERS portal, developing a botanical thesaurus to enable sophisticated search strategies, and electronic links to other databases such as MedWatch and poison control centers.

DIETARY SUPPLEMENT CURRENT GOOD MANUFACTURING PRACTICES (CGMPs)

Under DSHEA, another important arm of FDA's regulatory and surveillance activities used 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. FDA published a proposed rule for dietary supplement CGMPs on March 13, 2003, which would establish standards to ensure that dietary supplements and dietary ingredients are not adulterated with contaminants or impurities, and are labeled to accurately reflect the active ingredients and other ingredients in the product.

Examples of product quality problems the proposed dietary supplement CGMPs would help prevent are: superpotent and subpotent products, wrong ingredients, presence of contaminants (e.g., bacteria, pesticide, glass, and lead), under-filled containers, foreign material in a dietary supplement container, improper packaging, and mislabeling. The publication of the final rule on dietary supplement CGMPs remains a high priority for FDA. A 90-day public comment period on the proposed rule was extended 60-days and closed on August 11, 2003. During the comment period, FDA staff participated in two outreach meetings and an FDA-sponsored satellite downlink, as well as three outreach meetings organized by industry groups to ensure that dietary supplement manufacturers (especially small manufacturers) and other interested parties were familiar with the proposal.

Due to the volume of comments and requests by commenters, FDA extended the time period in order to receive additional public comments. We are currently reviewing over 1600 pages of

comments, which include more than 400 substantive comments that are being carefully analyzed. We plan to publish a final rule once this evaluation is completed. We recognize the importance of having dietary supplement CGMPs in place and we are moving forward to complete this regulatory priority under DSHEA. This rule will give consumers greater confidence that the dietary supplements that they choose to use will have the identity, strength, purity and composition that they are represented to have.

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. On December 18, 2002, the FDA Commissioner announced the Consumer Health Information for Better Nutrition Initiative. The focus of this effort is to make available more and better 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 makers 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 dietary supplement marketers who make false or misleading claims.

In a July 10, 2003, status report on the Better Health Initiative, FDA unveiled a process to review health claims. In addition, the Agency announced enhanced enforcement activity against dietary supplement manufacturers and others who make misleading claims about health benefits that are not based on science. These enforcement activities are described below.

ENFORCEMENT ACTIONS

At the core of FDA's DSHEA enforcement efforts is our commitment to work with industry in order to enhance 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 actions 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 the FTC. FDA regulates the safety, manufacturing, and labeling of dietary supplements, while the FTC has primary responsibility for regulating the advertising of these products. Over the last few years, the FDA and the FTC have worked well 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 the FTC and other law enforcement and public health authorities in the U.S. and abroad.

Since October 1, 2003, FDA has conducted 180 domestic inspections of dietary supplement manufacturers, issued 103 warning letters and “cyber letters” to marketers of dietary supplement products, seized products worth almost \$9.65 million, supervised the voluntary destruction of almost \$8 million worth of products promoted with unsubstantiated dietary supplement claims or that were unapproved drugs, and obtained permanent injunctions against 3 firms distributing misbranded or unapproved drugs.

FDA enforcement has extended to our nation’s borders, where we have refused importation for 1171 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 or 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. 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.

HIGHLIGHTS OF RECENT ENFORCEMENT ACTIONS

Royal Tongan Limu

In October 2003, FDA witnessed the voluntary destruction of 90,000 bottles worth \$2.7 million of Royal Tongan Limu, a liquid dietary supplement distributed by Dynamic Essentials, a subsidiary of NBTY, Inc. The firm was initially warned in a 2002 FDA “cyber letter” that website claims to treat various diseases such as cancer, arthritis, and Attention Deficit Disorder caused their products to be in violation of the law. Despite the warning, the product remained in distribution channels and, therefore, FDA recommended the seizure action. Dynamic Essentials ceased operation and no longer promotes or sells the products on its website.

Germanium Sesquioxide

In October 2003, FDA refused an entry of 20 kilograms of bulk germanium sesquioxide valued at \$16,500, destined for use in human dietary supplements. Germanium has caused nephrotoxicity (kidney injury) and death when used chronically by humans, even at recommended levels of use.

Jean’s Greens

In September 2003, at FDA’s request, the U.S. Marshal seized herbal tea products known as Forticel and Forticel Mix from Jean’s Greens in Norway, New York. The products claimed to treat and cure various life-threatening and serious illnesses such as cancer, thus causing the products to be unapproved drugs. FDA warned Jean’s Greens in November 2001 to change its labeling for the products. The firm failed to comply. The value of the seized goods was more than \$4000.

Seasilver

In June 2003, U.S. Marshals seized \$7 million worth of Seasilver, a liquid multi-vitamin/mineral/amino acid dietary supplement. The marketer, SeasilverUSA, promoted Seasilver, on the Internet and in marketing materials, as a safe and effective treatment for 650 serious diseases, including AIDS, cancer, diabetes, hepatitis, and arthritis. On March 8, 2004, Seasilver USA, Inc., and Americaloe, Inc., of Carlsbad, California, and their principals, signed a consent decree of permanent injunction in which they agreed to stop manufacturing and distributing violative products, including “Seasilver.” In addition, Seasilver USA, Inc. and Americaloe, Inc. will destroy the seized products at their expense and will pay liquidated damages for \$10,000 per day for any future violation of the consent decree. Under a settlement with the FTC, entered on March 4, 2004, the Seasilver defendants and the individual distributors agreed to pay \$4.5 million in consumer redress.

Coral Calcium

In June 2003, FDA issued warning letters to 18 firms, which operate 24 websites marketing multiple coral calcium products as effective treatments or cures for a variety of diseases and conditions including cancer, multiple sclerosis, lupus and heart disease. One product, Coral Calcium Supreme, was promoted in nationally televised 30-minute infomercials featuring Kevin Trudeau and Robert Barefoot. In June, on FDA’s behalf, U.S. Marshals seized \$2.6 million worth of Coral Calcium Supreme. In a separate action, FTC charged the marketers of Coral Calcium Supreme with making false and unsubstantiated claims that the product can treat or cure diseases and stipulated preliminary injunctions were entered against Trudeau, Barefoot, Shop America LLC and Deonna Enterprises, Inc. In December 2003, a U.S. District Court entered a

Consent Decree of Condemnation and Permanent Injunction against Shop America prohibiting Shop America and its directors, officers, agents, representatives from promoting any products as a treatment for disease.

SIGRA

In June 2003, FDA warned consumers not to purchase or consume SIGRA, STAMINA Rx and STAMINA Rx for Women, Y-Y, Spontane ES and Uroprin, manufactured by NVE Pharmaceuticals, Inc., in Newton, New Jersey and distributed by Hi-Tech in Norcross, Georgia. These products, which were marketed as dietary supplements for sexual enhancement, were found to contain the prescription drug ingredient tadalafil, which could cause a drastic lowering of blood pressure when combined with prescription drugs containing nitrates. Tadalafil is the active ingredient in Cialis, an Eli Lilly product approved in Europe to treat male erectile dysfunction. Despite FDA's warnings, the defendant and his related businesses repeatedly sold dietary supplements that claimed to treat obesity and erectile dysfunction. Hi-Tech recalled the products and in September 2003, a U.S. District Court Judge entered a Consent Decree of Permanent Injunction enjoining Hi-Tech Pharmaceuticals, National Urological Group, National Institute for Clinical Weight Loss, American Weight Loss Clinic, United Metabolic Research Center, and the President of these corporations, from distributing unapproved new drugs and misbranded drugs.

Global Source and Consulting, Inc.

In June 2003, a U.S. District Court entered a Consent Decree of Condemnation and Destruction for the seized products from Global Source and Consulting, Inc., which included 450 bottles and 57,000 bulk capsules of 20 dietary supplement products worth \$19,000. Global Source agreed to destroy the products and to cease manufacture and marketing of “Vitamin Hut Scientific Cholesterol Support Program” or any similar red yeast rice product containing lovastatin, or any other drug product that is a new drug unless and until an approved new drug application is in effect for such product.

Severe Acute Respiratory Syndrome (SARS)

In May 2003, in an immediate response, FDA and FTC warned website operators, manufacturers and distributors to remove misleading or deceptive Internet claims that their products may prevent, treat or cure SARS. An internet “surf” conducted by FTC, FDA and the Ontario Consumer and Business Services, found over 40 sites promoting a variety of SARS treatment and/or prevention products. The products include dietary supplements containing ingredients such as colloidal silver, ascorbic acid, beta glucan, pycnogenol, and oregano oil. FDA sent warning letters to 8 Internet firms promoting dietary supplement products to treat or prevent SARS. FTC also notified violative firms that they were subject to possible civil or criminal actions under the FTC Act.

Gero-Vita International, Inc.

In May 2003, the FTC filed a complaint against Glenn Braswell and four of his corporations for making false and unsubstantiated claims that several products marketed as dietary supplements are “scientific breakthroughs” to treat or cure numerous serious medical conditions. FDA

provided technical assistance and scientific support to FTC for this action. Products identified in the complaint were: Lung Support Formula, which claimed to cure or ameliorate asthma, emphysema, smoking damage and other respiratory problems; Antibetic Pancreas Tonic, which claimed to treat or cure diabetes and to lower blood sugar levels; and GH3 and GH3 Romanian Youth Formula, which claimed to extend life and prevent or treat Alzheimer's disease and other forms of dementia; Chitoplex to promote weight loss and reverse obesity without diet or exercise; and Testorex, which claimed to treat erectile dysfunction.

Nature's Youth

In April 2003, FDA announced that Nature's Youth, LLC, of Centerville, Massachusetts, voluntarily destroyed approximately 5700 boxes of its misbranded product, "Nature's Youth hGH" worth \$515,000. The action followed FDA's advisory that the products appeared to be misbranded by labeling that included unsubstantiated "structure and function" claims that the product would, among other things, "improve physical performance, speed recovery from training, increase cardiac output, and increase immune functions."

Street Drug Alternatives

On March 31, 2003, FDA sent Warning Letters to 8 firms after an investigation revealed that the firms sold "street drug alternative" products marketed for "recreational" purposes with claims that they would produce such effects as euphoria, a "high", or hallucinations. These street drug alternatives cannot meet the legal definition of a dietary supplement because they are not intended to supplement the diet, to promote health or to reduce the risk of disease. The 8 letters

were targeted primarily to manufacturers of products that contained ephedrine or norephedrine hydrochloride.

In 2001, FDA brought a seizure and injunction action against a purported supplement manufacturer that marketed its products as illegal street drugs. The case, *U.S. v. Undetermined Quantities of Articles of Drug, Street Drug Alternatives . . . et al.* showed that Hit Products, Inc., and Organic Diversions, Inc., marketed products made from a mixture of herbs that promised users effects comparable to illegal street drugs. FDA categorized these products as “street drug alternatives” and seized them as misbranded and unapproved new drugs in violation of the FD&C Act. FDA sought the destruction of the seized goods and an injunction barring defendants from future FD &C Act violations. In granting this relief, the court found FDA’s position on street drug alternatives “highly persuasive” and criticized the defendants’ characterization of the products as dietary supplements as a “veiled attempt to circumvent” the FD&C Act. The court “declined to carve out a statutory loophole for drug manufacturers attempting to profit from the illegal drug epidemic by masquerading potentially dangerous substances as legitimate dietary supplements.”

Ancom Anti-Hypertensive

In February 2003, FDA investigators found that Ancom Anti-Hypertensive Compound tablets, which were marketed on the Internet and in retail stores as dietary supplements, contained several prescription drug ingredients, including reserpine, diazepam (Valium), promethazine, and hydrochlorothiazide. Best Life International, the manufacturer, ceased distribution and recalled the product. Subsequently in May 2003, Best Life International issued a voluntary recall and warned consumers not to buy or consume its product called, Viga. Viga, marketed as a dietary

supplement, was found to contain sildenafil, the active ingredient in Pfizer's Viagra. Sildenafil can cause life-threatening lowering of blood pressure when taken with nitrates.

Unsubstantiated Claims for Enhanced Athletic Performance

In February 2003, based upon the conclusions of the RAND study, FDA warned 26 firms to cease making unproven claims that ephedrine-containing dietary supplements enhance athletic performance. Since performance enhancement was one of the two principal ways in which ephedra products have been marketed, the impact of these warning letters was substantial. On February 5, 2004, FDA officials accompanied U.S. Marshals in a seizure of ephedra-containing dietary supplements Betatrim, Thermbuterol, and Stacker 2, from *Musclemaster.com* in Northboro, Massachusetts. The firm failed to comply with FDA's warning to stop making unsubstantiated athletic performance claims on its websites. The value of the 900 bottles of seized goods was approximately \$19,308.

Yellow Jackets and Black Beauties

In January 2003, FDA and the U.S. Marshal's Service served an inspection warrant that would allow FDA to witness the voluntary destruction of \$4 - 5 million worth of products known as "Yellow Jackets" and "Black Beauties." The warrant was served at NVE Pharmaceuticals, Inc., the manufacturer of the products, located in New Jersey. A distributor in the Netherlands promoted the products on the Internet as alternatives to street drugs. Yellow Jackets and Black Beauties are "street terms" for controlled substances and were sold as herbal street drug alternatives. In September 2002, FDA became aware of the tragic death of a 16-year old high school football player who had taken Yellow Jackets. FDA placed the products on Import Alert on October 7, 2002.

EverCLR

On December 16, 2002, U.S. Marshals seized approximately 3,000 bottles of EverCLR, a dietary supplement, valued at more than \$100,000. EverCLR was marketed by Halo Supply Company of San Diego, California, a “natural” treatment for viruses such as the herpes virus and “cold and flu protection.” None of these claims were substantiated. FDA charged that EverCLR was an unapproved and therefore, illegal, new drug because it was promoted to treat and prevent specific diseases and conditions. Because EverCLR’s labeling lacked adequate directions for use, FDA also charged that it was misbranded

Calm Focus

In August 2002, FDA issued a Warning Letter to Better Way Kids. This firm distributed “Calm Focus,” a product promoted to treat Attention Deficit Disorder and Hyperactivity Disorder. The firm characterized its product as a “natural alternative to Ritalin” and claimed that it was “formulated to energize neurotransmitters in the brain.” The Warning Letter made clear that dietary supplements may not make disease claims or unsubstantiated structure/function claims. The firm corrected its product claims.

U.S. v. Syntrax Innovations, Inc., et. al

U.S. v. Syntrax Innovations, Inc., et al, involved a substance called Triax, marketed by Syntrax as a dietary supplement for the treatment of obesity and to promote weight loss. FDA scientists determined that the product contained a potent thyroid hormone called, tiratricol, that if taken in sufficient quantity can cause heart attacks and strokes. FDA alleged that Triax could not be a dietary supplement because it was promoted to treat a disease (obesity) and because it did not

contain any of the dietary ingredients identified in DSHEA. In February 2001, the court entered an injunction barring the distribution of Triax.

U.S. v. Lane Labs USA, Inc. and Andrew Lane

FDA brought an injunction action against Lane Labs USA, Inc., Andrew Lane and against three of Lane Labs' products, including its shark cartilage product, BeneFin. Lane Labs claimed that two of these products were dietary supplements, but the company promoted those products for the treatment of cancer and HIV. The third product is a skin cream promoted for the treatment of skin cancer. FDA contended that the disease claims caused all three of these products to be an unapproved, and therefore illegal, new drugs and misbranded drugs.

Brain Nutrient Capsule

United States v. Undetermined Quantities of Cases of an Article of Food and Drug Labeled in Part: Brain Nutrient Capsule, involved a dietary supplement product offered as a supplementary treatment for mental retardation, cerebral palsy, and epilepsy. The product's distributor claimed that it "has the function of increasing the intelligence, elevat[ing] the intelligence quotient (IQ) and promoting growth." FDA alleged that these claims were baseless.

RULE REMOVING DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS (EPHEDRA) FROM THE MARKET

Under DSHEA, a dietary supplement is adulterated if, among other reasons, it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended in the labeling, or if the labeling is silent, under ordinary conditions of use.

On February 11, 2004, FDA applied DSHEA's unreasonable risk standard and issued a final rule declaring dietary supplements containing ephedrine alkaloids (ephedra) adulterated. The rule will have the effect of removing dietary supplements containing ephedrine alkaloids from the marketplace and will become effective April 12, 2004.

Last winter, FDA issued letters to manufacturers of dietary supplement containing ephedra to notify them of its planned action. The Agency's history in reviewing ephedra under DSHEA is substantial. FDA has had long-standing concerns about potential risks associated with dietary supplements containing ephedra.

FDA ACTION ON SUPPLEMENTS CONTAINING ANDROSTENEDIONE

On March 11, 2004, FDA announced action on androstenedione ("andro"), as a result of the Agency's concerns about its safety. Andro acts like a steroid once it is metabolized by the body and therefore can pose similar kinds of health risks as steroids. These products are generally marketed as dietary supplements to enhance athletic performance based on their claimed anabolic and androgenic properties to stimulate muscle growth and increase production of testosterone.

FDA sent warning letters to 23 companies asking them to cease distributing products sold as dietary supplements that contain androstenedione and warning them that they could face

enforcement action if they do not take appropriate actions. The letters stated that FDA is not aware of any information demonstrating that androstenedione was lawfully marketed as a dietary ingredient in the U.S. before October 15, 1994, nor is FDA aware of any information demonstrating that this ingredient has been present in the food supply as an article used for food in a form in which the food has not been chemically altered. In the absence of such information, dietary supplements containing “andro” are subject to the pre-market notification requirement for a new dietary ingredient. Because no notification was submitted for “andro”, dietary supplements containing “andro” are considered adulterated.

The warning letters further state that, based on what FDA knows now, the Agency is aware of no history of use or other information establishing that a dietary supplement containing androstenedione will reasonably be expected to be safe. There is existing evidence that the use of androgenic steroid precursors such as androstenedione may have long-term adverse health consequences. If a manufacturer files a new dietary ingredient notification to the Agency, FDA will evaluate whether specific products are adulterated.

Mr. Chairman, thank you for this opportunity to testify. I am happy to answer your questions.