



DIETARY SUPPLEMENT ENFORCEMENT REPORT

The Food and Drug Administration ("FDA") is committed to ensuring that consumers have access to truthful and non-misleading information about products related to their health. This means, in some cases, facilitating the free flow of information to consumers. In other cases, it means protecting them against misinformation. In regulating dietary supplements, FDA has proceeded on both fronts.

This report details FDA's current dietary supplement enforcement efforts and its prospective enforcement plan. At the core of FDA's efforts is its commitment to the legitimate manufacture, sale, and use of dietary supplements, balanced against a zero-tolerance approach to fraudulent or otherwise illegal practices. Achieving these goals relies on a number of strategies. First, enforcement actions against dietary supplement marketers who break the law is critical. The growth of the Internet has afforded marketers ease of access and the ability to operate outside national boundaries. To counter this, FDA must coordinate its efforts with federal, state, and international law enforcement agencies. At the same time, FDA must empower consumers with clear and accurate information so that they can make informed choices about dietary supplements.

I. Background

A. Consumer Use of Dietary Supplements

The dietary supplement industry is among the world's fastest growing industries. Supplement sales are reported to have reached \$17.1 billion in 2000. Consumer spending in this area nearly doubled from 1994 to 2000 and spending continues to grow at a rate of more than 10% per year. A recent survey by PREVENTION Magazine found that over 158 million consumers use dietary supplements. They use them in an effort to achieve self-care goals and as a means of ensuring good health. They also use them for "medicinal" purposes such as treating and preventing various illnesses, colds, and flu. Over time, the market for these supplements likely will grow due to factors such as the aging of the baby-boom generation, increased interest in self-sufficiency, and advances in science that are uncovering new relationships between diet and disease.

But with the growing use of dietary supplements comes increased risks of fraud and consumer injury. Promotions for fraudulent products appear regularly in newspaper and magazine ads and in television "infomercials." They accompany products sold in stores and through mail-order catalogs. The Internet provides myriad

opportunities for deception and, because it is a worldwide communications system, U.S. citizens are susceptible to fraud from sources outside this country.

This wave of promotions leads many consumers to buy fraudulent health products. Hoping to cure illness or improve their appearance, consumers often fall victim to products and devices that cheat them out of their money and steer them away from proven treatments. These fraudulent products pose specific dangers including:

- substituting unproven treatments for proven medical treatments;
- harmful interactions with prescription or over-the-counter drugs;
- taking products that have no health benefits or that have adverse effects; and
- economic loss.

B. The Dietary Supplement Health and Education Act

1. *Background*

In October 1994, the Dietary Supplement Health and Education Act ("DSHEA") was signed into law. DSHEA acknowledges that millions of consumers believe that dietary supplements may provide health benefits. Congress's intent in passing it was to strike a balance between consumer access to dietary supplements and FDA's authority to act against supplements that present safety problems or bear false or misleading labeling. DSHEA creates a new regulatory framework for the safety and labeling of dietary supplements.

FDA is committed to enforcing DSHEA in a manner that effectuates Congress's intent. Thus, the agency will foster the communication of truthful and non-misleading information about dietary supplements to consumers. At the same time, when a product risks consumer injury or is marketed using misinformation, FDA will move quickly to take the product off the market. FDA likewise will act to prevent manufacturers and distributors of such products from engaging in fraudulent practices.

2. *Definition of a Dietary Supplement*

DSHEA defines a dietary supplement as a product that is ingested, is intended to supplement the diet and, among other requirements, contains a "dietary ingredient." Dietary ingredients may include vitamins, minerals, herbs or other botanicals, amino acids, and dietary substances such as enzymes. Dietary ingredients also can be metabolites,

constituents, extracts, concentrates, or combinations of these ingredients. Supplements come in forms including tablets, capsules, liquids, and bars. The product must be labeled as a dietary supplement and information on its label must not represent it as a conventional food or a sole item of a meal or diet.

3. *Permitted Claims*

Marketers of dietary supplements may make a number of claims about their products:

- Health claims authorized by FDA in a regulation ñ such as the assertion that calcium can reduce the risk of osteoporosis ñ may be made if the product meets the requirements to bear the claim. In light of the appellate court decision in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), FDA has developed guidance on when it will exercise enforcement discretion (i.e., decline to initiate enforcement action) regarding qualified health claims not authorized by regulation. Additional information about health claims can be found on FDA's Web site at www.cfsan.fda.gov/~dms/ds-labl.html.
- Statements about a supplement's use against classic nutrient deficiency diseases (e.g., scurvy) are permitted, provided that the statements disclose the prevalence of the disease in the United States.
- Marketers may also describe the supplement's effects on the structure or function of the body. Examples of permissible structure/function claims include: "relieves stress and frustration," "helps support cartilage and joint function," and "improves memory." To make these claims, manufacturers must have substantiation that the statements are true and not misleading and the product label must include the following disclaimer: "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."

DSHEA does not subject dietary supplements to FDA pre-market approval. But a firm is responsible for ensuring that its product is safe and that structure/function claims about it are substantiated by adequate evidence to show that they are not false or misleading.

4. *Prohibited Claims*

The Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits labeling claims that are false or misleading. An unsubstantiated dietary supplement claim is false or misleading and therefore violates the FDCA. Nor can a marketer promote a supplement to treat a disease. A dietary supplement that is promoted to treat, prevent, or cure a disease or condition is considered an unapproved, and therefore illegal, new drug.

II. Current Enforcement Efforts

A. Development of Enforcement Activities

Health fraud can come to FDA's attention in a variety of ways. FDA may identify fraudulent products through market-place surveys; inspections; Internet searches; adverse event reports; consumer complaints; informants; or through referrals from other government agencies.

Products that present a direct health hazard to consumers are FDA's highest priority. These products either have caused injury or death or pose a significant risk of illness or injury. When FDA encounters such products, it uses all available civil and administrative remedies to remove them from the market. FDA also uses publicity to warn consumers and health professionals about the products.

Products that are not themselves hazardous can still present an indirect health hazard in that consumers may delay or forego proven medical treatments or drug therapies. Examples include unproven products promoted for the treatment of cancer, diabetes, arthritis, heart disease, and high blood pressure.

When a problem arises with a product, FDA can take a number of actions to protect the public. For dietary supplements, as with other products, the agency may initially work with the product's marketer to correct the problem voluntarily. If that fails, the agency may bring a lawsuit to seize the product and enjoin the firm marketing it. When warranted, FDA also seeks criminal penalties – including prison sentences – against parties who break the law.

FDA's dietary supplement enforcement efforts stem from this regulatory framework. But in the last year, the agency has taken steps never taken before. For the first time, FDA has seized dietary supplements based on unsubstantiated claims about their effect on the body's structure or function. These cases will provide a model for future enforcement actions. FDA likewise remains committed to

consumer and industry education about the labeling and use of dietary supplements. The agency has also leveraged its resources through expanded relationships with federal, state, and international enforcement authorities.

B. Scope of Enforcement Activities

FDA's Center for Food Safety and Applied Nutrition ("CFSAN") and Office of Regulatory Affairs have focused their dietary supplement enforcement budgets principally on targeted inspections and, where appropriate, recommending enforcement action against parties who violate DSHEA. CFSAN has also published industry guidance documents and consumer education materials regarding dietary supplements.

Consistent with its interest in this area, Congress earmarked \$500,000 in FDA's fiscal 2002 budget to be spent on dietary supplement enforcement. In fulfilling this mandate, much of FDA's expenditures have covered the salaries of personnel conducting enforcement activities. Other expenditures include support staff salaries, management expenses, and training.

In terms of the strategies used to enforce DSHEA, FDA has proceeded on several fronts:

1. *Traditional Enforcement Activities*

a. Inspections

Last year, FDA inspected more than eighty dietary supplement marketers under the agency's authority to examine facilities used to manufacture, process, or hold foods. A number of these inspections led to the voluntary correction of identified violations. For example:

- FDA conducted a May 2002 inspection of Fresh Vitamins, a manufacturer of Noni Fresh Juice. Fresh Vitamins marketed its product to treat conditions ranging from immune system disorders to arthritis, malaria, and alcohol addiction. Following the inspection, the firm's president stated that he had removed impermissible claims from the firm's Web site and that he was educating himself on FDA policy regarding dietary supplement claims.

- Following a May 2002 inspection of Health Ventures, a manufacturer of Miracle Bust, an FDA investigator witnessed the destruction of the company's inventory. The company signed an affidavit stating that it would voluntarily stop the sale and distribution of Miracle Bust, delete references to it on its Web site, and refrain from placing future orders from its contract manufacturer.

b. Warning Letters

FDA may issue a warning letter when an inspection produces evidence of a statutory violation. The letter advises the recipient of the violation and warns that failure to correct it may result in agency action without further notice. In the past year, FDA has aggressively used this tool in its dietary supplement enforcement efforts. The agency issued seventeen dietary supplement warning letters, with products containing synthetic ephedrine receiving particular attention. Marketers promote these products for use in weight loss, energy enhancement, and to increase libido. But the presence of synthetic ephedrine places the products outside the definition of a dietary supplement. In mid-June, FDA sent seven warning letters to manufacturers of products containing synthetic ephedrine. All but one of the companies have since stopped marketing their products. FDA may inspect the remaining company and is considering judicial action to prevent further violations.

Warning letters have not been limited to marketers of synthetic ephedrine products. In August 2002, for example, FDA issued a warning letter to Better Way Kids. This firm distributes "Calm Focus," a product promoted to treat Attention Deficit Disorder and Hyperactivity Disorder. The firm characterizes its product as a "natural alternative to Ritalin" and claims that it is "formulated to energize neurotransmitters in the brain." The warning letter makes clear that dietary supplements may not make disease claims or unsubstantiated structure/function claims. The firm is correcting its product claims.

c. Seizures and Injunctions

If a product violates the FDCA, FDA may bring a court action to seize and destroy it. FDA may also sue the manufacturer or distributor of the product to enjoin further violations. This is especially true where the manufacturer/distributor is a repeat offender or poses a risk of future violations.

Over the summer, FDA filed two seizure actions against dietary supplements making unsubstantiated claims about their effect on the structure or function of the body. The first action, United States v. Undetermined Quantities of Cases of an Article of Food and Drug . . . Labeled in Part: BRAIN NUTRIENT CAPSULE, No. 02-4997 (E.D. N.Y.), involves a product offered as a supplementary treatment for mental retardation, cerebral palsy, and epilepsy. The product's distributor claims that it "has the function of increasing the intelligence, elevat[ing] the intelligence quotient (IQ) and promoting growth" FDA alleges that these claims are baseless. It will soon move for a default judgment condemning the seized products.

The second action, United States v. 172/100 Capsule Bottles, More or Less, of an Article of Food Labeled in Part: Kirkman Taurine 325 mg Dietary Supplement Capsules, No 02-l 337 FR (D. Or.), concerns a product offered as a supplementary treatment for autism. Materials promoting the product state, "Dr. Jeff Bradstreet, a physician in Palm Bay, Florida who treats autistic patients reports good success using Taurine." The materials further assert that "[t]aurine may be beneficial in developmental disorders." FDA alleges that there is no scientific support for these claims. The product's manufacturer has indicated that it will take corrective action and that it will not oppose the product's condemnation and destruction.

FDA has also brought seizure and injunction actions against purported supplement manufacturers that market their products as illegal street drugs. These cases include:

- United States v. Undetermined Quantities of Articles of Drug, Street Drug Alternatives . . . et al. ("Hit Products"), 145 F.Supp.2d 692 (D. Md. 2001). Hit Products, Inc., and Organic Diversions, Inc.,

- were marketing 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 FDCA. FDA sought the destruction of the seized goods and an injunction barring defendants from future FDCA violation. 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 FDCA. The court "decline[d] to carve out a statutory loophole for drug manufacturers attempting to profit from the illegal drug epidemic by masquerading potentially dangerous substances as dietary supplements."
- FDA is currently investigating other possible cases of street drug alternatives. These investigations include firms that market ephedrine as a substitute for illegal amphetamines. FDA anticipates that these investigations will lead to seizures and injunctions similar to the relief obtained in Hit Products.

FDA seizure and injunction actions also extend to supplement marketers who violate DSHEA's proscription of disease claims. Examples include:

- U.S. v. Lane Labs USA, Inc. and Andrew Lane, No. 99-5782 (WGB) (D. N.J.). This is a pending injunction action that involves several of Lane Labs' products, including its shark cartilage product. Lane Labs markets this product as a dietary supplement, but makes unsubstantiated cancer treatment claims about it. FDA contends that this disease claim causes the product to be an unapproved, and therefore illegal, new drug.
- United States v. Syntrax Innovations, Inc., et al, 149 F.Supp.2d 880 (E.D. Mo. 2001). This case involves a drug called Triax Metabolic Accelerator, marketed by Syntrax as a dietary supplement for the treatment of obesity and to promote weight loss. FDA scientists determined that the product contains tiratricol, a hazardous compound that 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.

Finally, FDA has seized products marketed as dietary supplements that contain synthetic ephedrine. In March of this year, for example, FDA filed a consent decree signed by the parties in United States v. 1009 cases et al., No. 2:01CV-820C (D. Utah). This case involved the seizure of nearly \$3 million worth of Amp II Pro Drops from a company doing business as E'OLA International. Although labeled as a supplement, the product contained synthetic ephedrine. FDA alleged that the product violated the law because synthetic ephedrine is not a dietary ingredient. Accordingly, a product containing synthetic ephedrine is not a dietary supplement. The agency also alleged that the product ñ which was marketed to treat obesity ñ made illegal disease claims. The consent decree required the product's destruction and prohibited E'OLA from manufacturing or distributing products that violate the FDCA.

d. Criminal Enforcement

FDA bases its criminal prosecutions primarily on the public health threat level, indications of criminal intent, the scope of the violation, and the potential impact of effective prosecution. Relying on these factors, the agency has pursued a number of successful criminal cases:

- U.S. v. Diane Eckert-Kunick, No. MG-F-02-2093 (E.D. Cal.). In 1996, Diane Eckert-Kunick, along with her parents, formed New Gaia Products ("NGP"). The company manufactured, distributed, and sold dietary supplements including colloidal gold, colloidal silver, and colloidal titanium. Eckert-Kunick also distributed promotional literature claiming that NGP products cured cancer, rheumatoid arthritis and heart disease. In April 2002, Eckert-Kunick was convicted of introducing unapproved new drugs into interstate commerce.

She received a sentence of four months incarceration in a community correctional center.

- U.S. v. Cap-Tab Nutritional Formulating and Manufacturing Inc., No. 99-CR00245J, (S.D. Cal.). This case stems from an allegation that Jack Watkins, Sharon Gross, and Lyndon Dellis, all officers of Cap-Tab, conspired and knowingly substituted low-price ingredients for the ingredients listed on the label of their dietary supplement product (encapsulated vegetable powders). In June 2002, Watkins was convicted of one count of introducing misbranded food into interstate commerce. The corporation was convicted of the same violation. Gross, Watkins, and Cap-Tab received sentences of 1 year's probation and were ordered to pay fines of \$500, \$250, and \$5000, respectively. Dellis received a sentence of 180 days incarceration followed by five years incarceration on a related state criminal conviction.
- U.S. v. Theodore Sosangelis and Thomas Knox, Nos. CR301-238, CR301-289 (D. Conn.). From January through July 2000, Knox and Sosangelis conspired to distribute counterfeit dietary supplements. Through their company, East Coast Ingredients ("ECI"), they produced an inexpensive version of legal supplements manufactured by Muscletech. After placing fake Muscletech labels on their products, Knox and Sosangelis sold them to customers who believed that they were purchasing legitimate Muscletech dietary supplements. In October 2001, Sosangelis pled guilty to one felony count of trafficking counterfeit goods in interstate commerce. He received a sentence of 3 years probation and was order to pay restitution of almost \$77,000. In February of this year, Knox also pled guilty to a felony count of trafficking counterfeit goods. He is scheduled to be sentenced later this month.

2. *Inter-Agency and International Enforcement*

a. Federal Trade Commission ("FTC")

With their mutual goal of consumer protection, FTC and FDA have a long-standing history of working together against health care fraud. The agencies operate under a liaison agreement regarding dietary supplements. FDA has primary responsibility for claims on product

labeling and FTC has primary authority over advertising claims. This shared jurisdiction permits the agencies to coordinate closely in their enforcement efforts. In addition, the agencies have jointly authored several consumer education pieces, including a "Facts for Consumers" brochure focused on spotting false claims and health fraud.

b. Other Agencies

FDA's relationship with FTC has been an effective tool in the fight against health care fraud. Because of the sheer volume of dietary supplement products, as well as easy access to consumers from foreign locations, FDA has also forged partnerships with other federal, state, and international enforcement agencies. These links have fostered successful initiatives, including the following:

- U.S./Canada Health Fraud Summit: FDA and FTC sponsored a Health Fraud Summit in May 2002. More than thirty management-level participants from U.S. and Canadian law enforcement agencies attended. The primary objective of the summit was to develop procedures to enhance interagency cooperation. The participants have since formed a steering committee, which will address the action items identified at the summit.
- U.S. Customs Service: FDA has worked closely with the U.S. Customs Service to ensure that certain imported goods are targeted for automatic detention. These include potentially harmful products marketed as dietary supplements. For example, at FDA's request, the Customs Service detained supplements containing aristolochic acid, a botanical product associated with kidney damage and cancers of the urinary tract.
- Operation Cure.All: In 1997, FTC, FDA, Health Canada, and various state Attorneys General began an ongoing law enforcement and consumer education campaign against the fraudulent marketing of supplements and other health products on the Internet. The agencies have since moved to stop Internet scams for products purporting to cure cancer, HIV/AIDS, and other life-threatening diseases. Collaboration on "Operation

Cure.All" helps FDA to communicate to the Internet community that law enforcement agencies are working together to combat health fraud.

- Health Fraud Working Group: In 1992, FDA began sponsoring a National Health Fraud Working Group. The group is comprised of representatives from the Association of Food and Drug Officials, state Attorneys General, FTC, Health Canada, and FDA. It meets on a regular basis to promote coordinated regulatory activities and information exchange.

3. *Consumer and Industry Education*

Seizures, injunctions, and other enforcement tools are only part of an effective program to implement DSHEA. Equally critical is consumer and industry education. Through written materials and Web-based resources, FDA has provided consumers with the means to make informed choices about dietary supplements. Examples of these materials include CFSAN's "Overview of Dietary Supplements" and "Tips for the Savvy Supplement User" (both available at <http://www.cfsan.fda.gov/~dms/ds-info.html>). CFSAN has also published consumer advisories concerning dangerous products. For example, in March of this year, it issued an advisory about dietary supplements containing Kava, a botanical ingredient (www.cfsan.fda.gov/~dms/addskava.html). Kava-containing products have been associated with liver conditions including hepatitis, cirrhosis, and liver failure. The advisory recommends that persons with liver disease, or persons experiencing symptoms of liver disease, consult a physician before using a Kava-containing supplement.

FDA has likewise communicated to industry those practices that are permissible under DSHEA. It has done so through guidance documents and information posted on the agency's Web site. For example, FDA's "Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide" discusses compliance with the agency's regulations implementing DSHEA's labeling provisions. FDA's "Structure Function Claims Small Entity Compliance Guide" offers guidance to small businesses regarding the distinction between structure/function claims and disease claims.

III. Prospective Enforcement

In January 2000, FDA announced a dietary supplement enforcement strategic plan. The plan's goal is to produce a "science-based regulatory program that fully implements [DSHEA], thereby providing consumers with a high level of confidence in the safety, composition, and labeling of dietary supplements." As FDA works towards this goal in the months ahead, its enforcement efforts will proceed along several fronts.

A. Traditional Enforcement Activities

FDA will continue to inspect manufacturers and distributors of dietary supplements. As in the past, identified violations will produce enforcement responses ranging from warning letters to seizures and injunctions. In injunction suits, FDA may seek equitable disgorgement of profits from the defendants' illegal activities. Cases settled under consent decrees may contain liquidated damages provisions to deter future violations. FDA also will continue, where appropriate, to bring criminal prosecutions.

The newly modeled CFSAN Adverse Event Reporting System ("CAERS") will assist FDA's enforcement efforts. CAERS is designed to provide a single system to track and analyze all adverse event reports involving CFSAN regulated products (including dietary supplements). It will increase efficiency, speed processing time, and provide medical review for all serious adverse event reports. The first version of CAERS was tested in fiscal year 2002. It will next undergo modification based on user acceptability testing, with final implementation planned for June 2003.

FDA's enforcement efforts to date have covered a wide array of supplement products. Based on its experience in this area, the agency has identified certain products that are clearly problematic and which warrant close scrutiny. They include the following:

- Treatments for Life-Threatening Diseases: Scores of dietary supplements are offered to treat life-threatening diseases including cancer, HIV/AIDS, and lupus. Cancer products offer "miracle cures" by stimulating "cancer-fighting cells." Supplements for HIV/AIDS and other serious diseases promise to stimulate the immune system. These products are ineffective and rely on unsubstantiated claims. Worse, they may convince patients to delay or reject proven therapies.
- Weight Loss Products: Some of these supplements promise to stop cravings and burn fat. Others claim to prevent fat and cholesterol absorption, permitting weight loss without changes to diet. There is no evidence supporting the products'

effectiveness. "Effortless" weight loss remedies do not work and are directly tied to the public health concern about obesity.

- Autism Treatments: Parents of autistic children can be desperate and provide easy targets for unproven therapies. Marketers of dietary supplements for autistic children contend that their products promote more complete food digestion, thereby preventing neuro-toxic molecules that contribute to autism. This is a false and unsupported claim.
- Treatments for Behavioral Disorders: Like parents of autistic children, parents of children with behavioral disorders (e.g., Hyperactivity and Attention Deficit Disorder) are vulnerable targets for sham products. These parents want their children to behave normally and want to avoid "drugging" them. Supplements claiming to treat these disorders promise time-tested methods that offer an alternative to drug therapy. These products often claim to contain ingredients that respond to the neurochemical bases of the behavioral problem. In fact, the physiological causes of these disorders are not fully understood and these claims are patently false.
- Treatments for Mental Retardation and Down's Syndrome: Many of these supplements identify low intelligence in children as a disease. By promising to "increase the intelligence quotient," these products claim to treat conditions such as mental retardation and microcephalus. Other supplements target Down's Syndrome specifically, claiming to prevent or treat the effects of this condition (i.e., irregular development, organ damage, and mental retardation). These purported treatments are ineffective and lack a sound scientific basis.
- Colloidal Minerals: These products are specified for diseases including fibromyalgia, breast cancer, Alzheimer's, and ovarian cancer. The products claim to provide essential minerals and are premised on the false assertion that foods today do not contain needed nutrients because of soil depletion. This assertion gives rise to pervasive economic fraud.
- Supplements for Smokers: Some of these products claim a special formulation that protects the user from the harmful effects of smoking. Others maintain that their ingredients act upon the brain's neural-receptors to prevent nicotine craving. The only proven remedy against the effects of smoking is quitting. These sham products instead promote unproven treatments that do not work.
- Supplements for Drinkers: Some of these products claim to prevent hangovers. Others promise to prevent drunkenness and to lower the symptoms of alcohol consumption (e.g., high blood-alcohol levels, poor coordination, and memory impairment). One product falsely claims to be FDA approved. Apart from not

working, these products encourage irresponsible drinking, with its attendant dangers.

- Colloidal Silver Products: These products are promoted as alternatives to antibiotics intended for serious infectious diseases. They also are promoted to protect against anthrax. Colloidal silver is completely ineffective. It is marketed for use by children and can cause severe adverse consequences, including argyria (blue-gray discoloration of the skin caused by the ingestion of silver). This condition is irreversible.

By closely scrutinizing these products and, whenever possible, bringing enforcement actions, FDA sends a clear message that it will not tolerate fraudulent practices that victimize or endanger consumers.

B. Inter-Agency and International Coordination

FDA must continue to develop its relationships with other law enforcement agencies. This is especially important given the increasingly complex challenges faced by the agency. The Internet offers an example of these challenges. This medium provides unprecedented access to consumers ñ anyone with storage space in their home and a desk-top computer can market dietary supplements. As problematic, marketers can use the Internet to operate outside of national borders, beyond FDA's jurisdiction.

To accommodate these pressures, FDA will continue to coordinate its activities with other state and federal agencies. Because these agencies possess limited jurisdiction over sellers in foreign countries, FDA must also work with foreign governments. FDA has developed effective links with Canadian and Mexican enforcement authorities. It must now develop similar relationships with consumer protection agencies in Europe and elsewhere.

C. Industry and Consumer Education

Traditional enforcement actions and coordinated efforts with other agencies are necessary, but not sufficient, components of a dietary supplement enforcement regime. FDA must complement these measures with industry and consumer education.

1. *Industry Education*

FDA will continue to assist industry by providing guidance documents addressing the manufacture, labeling, and sale of dietary supplements. FDA also encourages industry to develop

"best practice" guidelines for dietary supplement manufacturers and distributors. These "best practices" must accompany an industry effort to identify outliers. The purveyors of products making disease claims, unsubstantiated structure/function claims, and street drug claims harm the supplement industry's credibility. Legitimate industry members therefore have a vested interest in curbing fraudulent operators.

FDA also recognizes the need for dietary supplement Current Good Manufacturing Practice requirements ("CGMPs"). The growing market for dietary supplements in a less restrictive regulatory environment risks quality-control problems. FDA has worked with industry and other interested parties to produce CGMPs that will address this and other concerns. FDA will soon publish proposed dietary supplement CGMPs. They will be followed by a public comment period, development and publication of final CGMPs, and establishment of an inspection program to ensure industry compliance.

2. *Consumer Education*

FDA will continue to protect consumers by bringing enforcement actions against supplement marketers and products that make false or misleading claims. But consumers must also be able to evaluate the accuracy of labeling claims and, with the assistance of health professionals when appropriate, determine which dietary supplements are right for them. Accordingly, FDA will continue to develop mechanisms, including expanded use of its Web site, to communicate critical information and useful strategies about dietary supplements to consumers. Coordination with consumer groups like the Better Business Bureau, and with professional groups like the American Medical Association, will help FDA to convey this information.

As important, FDA must research consumer understanding of labeling information. The agency must ensure that consumers understand structure/function claims and that they are not misled by labeling information. This research is critical to FDA's regulatory decisions.

IV. Conclusion

FDA's first concern is to protect the public health. Applied to dietary supplements, this means removing from the market harmful and fraudulent products as well as preventing dishonest operators from deceiving consumers. FDA's partnerships with federal, state, and international law enforcement agencies expand the agency's reach and impact. But for every marketer of misleading information that FDA puts out of business, another appears. Strong enforcement actions, vigilant oversight of the marketplace, and the legal authority to remove illegal products can help to deter misleading marketing. Consumer education is also critical. Successfully combating health fraud must include educating consumers to recognize fraud when they see it and warning them of the potential dangers that some products pose. Only through these steps can consumers make fully informed decisions about their health care purchases.

At the same time, FDA recognizes that DSHEA is meant to promote consumer access to legal, properly labeled dietary supplements. This points up the need to clearly demarcate proper manufacturing and marketing practices. The forthcoming CGMPs will play a key role in this regard and FDA will continue to provide guidance on areas of confusion. On industry's part, FDA strongly encourages it to develop and enforce "best practice" guidelines.

FDA faces a challenge in ensuring consumer access to dietary supplements, while protecting consumers from harmful products. The agency remains committed to finding new and more effective ways to address this challenge.

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