DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
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STATEMENT OF
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BEFORE THE
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING, AND THE DISTRICT OF COLUMBIA
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

OCTOBER 8, 2002

RELEASE ONLY UPON DELIVERY

THE REGULATORY FRAMEWORK UNDER THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT (DSHEA) OF 1994

In 1994, DSHEA created a unique regulatory framework for dietary supplements in the United States. Its purpose was to strike the right balance between providing consumers access to dietary supplements that they use to help maintain and improve their health and giving the Food and Drug Administration (FDA or the Agency) the necessary regulatory authority to take action against supplements that present safety problems, have false or misleading claims, or are otherwise adulterated or misbranded.

I reference the July 31, 2002 testimony before your subcommittee of Joe A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN). In that testimony we detailed FDA's actions as we commenced our regulatory and enforcement actions under DSHEA.

As a summary of the previous testimony, I would like to point out that the DSHEA regulatory framework for dietary supplements is primarily a postmarket program, as is the case for foods in general. Should safety problems arise after marketing, the adulteration provisions of the statute come into play.

Under DSHEA, a dietary supplement is adulterated if, among other things, it or any of its ingredients presents "a significant or unreasonable risk of illness or injury" when used as directed on the label, or under normal conditions of use if there are no directions. FDA bears the burden of proof to show that a product or ingredient presents such a risk. In addition, the Secretary of Health and Human Services (HHS) has the authority to declare that a dietary supplement or dietary ingredient poses an "imminent hazard" to public health or safety.

FDA recognizes the success of our effort will depend on new and continued partnerships with other government agencies, academia, health professionals, industry and consumers. The Agency is committed to continue its outreach to stakeholders by establishing stronger working relationships with them as well as leveraging resources and communicating accurate dietary supplement information. As part of its implementation guidance, in May 2002, FDA provided Congress with a "Dietary Supplement Strategic Plan Cost Out."

THE DIETARY SUPPLEMENT – EPHEDRA

The focus of this hearing is on ephedra. Congress defined the term "dietary supplement" in DSHEA. A dietary supplement is a product that, among other requirements, is ingested, 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 the diet, and contains a "dietary ingredient." The "dietary ingredients" in these products 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 the preceding types of ingredients. Dietary supplements may be found in many forms, such as tablets, capsules, liquids, or bars. DSHEA placed dietary supplements in a special category under the general umbrella of "foods," except where the product meets the drug definition.

Ma huang is one of several names for herbal products containing members of the genus Ephedra. A number of adverse effects, including hypertension (elevated blood pressure), palpitations (rapid heart rate), neuropathy (nerve damage), myopathy (muscle injury), psychosis, and memory loss, or even the more serious adverse effects of heart attacks, stroke, seizure and death, have been reported to FDA with products containing Ma huang or other species of Ephedra as ingredients. Adverse events related to these products are currently under investigation. Ephedra has been shown to contain various chemical stimulants, including the alkaloids ephedrine, pseudoephedrine and norpseudoephedrine, as well as various tannins and related chemicals.

The concentrations of these alkaloids depend upon many factors, such as the species, parts of the plant used, time of harvest, and geographical location. Ephedrine and pseudoephedrine are used in over-the-counter and prescription drugs. Many of these stimulants have known potentially serious side effects. Ephedra is sold in products for weight control, as well as in products promoted to boost energy levels or to enhance athletic performance. These products often contain other stimulants, such as caffeine, that may have synergistic effects and increase the potential for adverse effects.

FDA Advisory Committees – 1995-1996

In 1995, FDA convened a Working Group of the Food Advisory Committee Meeting on ephedra. They reviewed all the safety information available, including the known published literature on pharmacological issues and adverse event reports submitted to the Agency. This was followed in August 1996 by a meeting of FDA's Food Advisory Committee. The prevailing view coming out of these meetings was that FDA should seek to establish a safe dose for ephedra products.

FDA Proposed Rule – June 4, 1997

On June 4, 1997, FDA published a proposed rule on dietary supplements containing ephedrine alkaloids. Under the proposed rule, a dietary supplement would be adulterated if it contained eight milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggested or recommended conditions of use that would result in an intake of eight mg or more within a six-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids. The Agency also proposed to prohibit the use of ephedrine alkaloids in dietary supplements with other stimulants, such as caffeine; to require special labeling on dietary supplements containing ephedrine alkaloids, including a warning statement and a statement that the product should not be used for more than seven days; and to prohibit labeling claims that require long-term intake to achieve the purported effect (e.g., claims about weight loss or body building). FDA received over 14,000 comments, the vast majority opposing the proposed rule.

General Accounting Office (GAO) Study – May 1998

In May 1998, the House Committee on Science requested that the GAO examine the scientific basis for the ephedrine alkaloids proposal. On August 4, 1999, GAO released its report entitled: "Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids."

While GAO concluded that FDA was justified in determining that the number and nature of adverse event reports relating to dietary supplements containing ephedrine alkaloids warranted the Agency's attention, they expressed concerns about the use of the reported adverse events to support the proposed dosing level and the limit on duration of use. The GAO concluded that the Agency needed additional evidence to support these restrictions, recommending FDA "provide stronger evidence on the relationship between the intake of dietary supplements containing ephedrine alkaloids and the occurrence of adverse reactions that support the proposed dosing level and duration of use limits."

Partial Withdrawal of Proposed Rule & Review of Adverse Events – April 3, 2000

On April 3, 2000, FDA withdrew the portions of the ephedrine alkaloids proposed rule relating to the dosing level and duration of use limits for these products. It retained the proposed warning statement and prohibition on including other stimulant ingredients in dietary supplements containing ephedrine alkaloids. At the time of the partial withdrawal of the proposed warning statement, FDA stated that the Agency continues to have a public health concern about the use of dietary supplements containing ephedrine alkaloids. FDA announced the public release of additional adverse event reports (AERs) that FDA had collected since 1997, which brought the number of adverse events up to approximately 1,400 reports at that time. The Agency also released the results of separate reviews by two scientific divisions within FDA and four outside scientific experts, of all AERs on ephedra received by FDA between June 1, 1997 and March 31, 1999, approximately 160 AERs. These separate reviews concluded that a significant number of these AERs were probably or possibly associated with ephedra use. FDA also sought public input about the significance of the new information and expert reviews and requested the submission of any other information relevant to a safety assessment of these products.

HHS Public Meeting – August 2000

The Department of HHS Office of Women's Health (OWH) held a public meeting on ephedra in August 2000. FDA and two of its outside experts presented their reviews of the 160 AERs referenced above. Industry representatives and their scientific experts also made presentations, as did some consumers and others. In September 2000, OWH issued its report on ephedrine alkaloid dietary supplements (EADS) from the public meeting. They concluded:

> "Despite the established limitations of AERs, many of the adverse effects are biologically plausible based on the known pharmacologic effects of ephedrine alkaloids. The pharmacology of ephedrine is supported by a rich database, in contrast to the paucity of evidence on the benefits or risks of EADS in humans. The level of concern for continued use of EADS must be based on the totality of information available on ephedra and ephedrine alkaloids, including the AERs, results of human and animal studies, as well as what is known about the pharmacology and chemistry of these compounds.
>
> Given the current widespread use of EADS, a consumer education campaign about these products is warranted. Good manufacturing standards are needed, reasonable dose and duration levels determined, and warnings and contraindications clearly indicated on labels. A research agenda should be established. Therefore, the research community should take the next logical step by conducting a systematic review of the world's literature on ephedra. After compiling the state of the science and identifying the limitations and gaps of the current research, an appropriate agenda can be established. In this regard, the National Center for Complementary and Alternative Medicine of the National Institutes of Health already is requesting proposals to study herb-drug interactions."

New England Journal of Medicine – November 2000

In November 2000, the New England Journal of Medicine published an advance Internet copy of a review of 140 ephedra AERs by Drs. Christine Haller and Neil Benowitz. The results of the study showed that 31% of the cases were considered to be definitely or probably related to the use of supplements containing ephedra alkaloids and 31% were deemed to be possibly related. Among the adverse events that were deemed definitely, probably, or possibly related to the use of supplements containing ephedra alkaloids, 47% involved cardiovascular symptoms and 18% involved the central nervous system. Hypertension was the single most frequent adverse effect (17 reports), followed by palpitations, tachycardia or both (13); stroke (10); and seizures (7). Ten events resulted in death and 13 events produced permanent disability, representing 26% of the definite, probably and possible cases. The article concluded: "the use of dietary supplements that contain ephedra alkaloids may pose a health risk to some persons. These findings indicate the need for a better understanding of individual susceptibility to the adverse effects of such dietary supplements." I do want to call the subcommittee's attention to the fact that the article was based upon an expert review of some adverse events that FDA had provided Dr. Benowitz, as an FDA consultant.

Department of HHS's Office of Inspector General (OIG) – February 12, 2001

On February 12, 2001, the OIG published a report: "Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve." They made four recommendations:

1. Facilitate greater detection of adverse events by requiring manufacturers to report to FDA and to conduct greater outreach to health professionals and consumers;

2. Obtain more information on adverse event reports to generate stronger signals by establishing manufacturer and product registries and developing a new computer data base;
3. Obtain more information to assess signals by exploring the possibility of a monograph system, expedite the development of good manufacturing practices and assist the industry in standardizing ingredients; and
4. Disclose more useful information to the public.

The recommendation to require adverse event reporting for dietary supplements requires a change in the current law. Meanwhile, FDA has made changes in other areas, as a result of the OIG report. The dietary supplement adverse events reporting system is being greatly improved with the implementation of the new CAERS system next year. On September 17, 2002, FDA did a public outreach on a new action we will take when we are notified about an adverse event. Our new procedure will be to send a letter to the supplement manufacturer or distributor to alert them to the event. Also, the recently enacted Bioterriorism law requires both conventional food and dietary supplement manufacturers to register with FDA. FDA is currently drafting proposed regulations to implement this requirement.

Public Citizen Petition – September 5, 2001

On September 5, 2001, Public Citizen and Dr. Ray Woolsey petitioned HHS to ban the production and sale of dietary supplements containing ephedrine alkaloids on the basis that these products present "a significant or unreasonable risk of illness or injury." They claimed that these products are being promoted to young people as athletic performance enhancers. Public Citizen cited a March 2001 Health Canada advisory warning consumers not to use products containing ephedra. On January 31, 2002, Public Citizen petitioned HHS once again to ban products containing ephedra.

Mayo Clinic Proceedings – January 2002

The January 2002 *Mayo Clinic Proceedings* published an article "Adverse Cardiovascular Events Temporally Associated With Ma Huang, an Herbal Source of Ephedrine." They analyzed 37 patients and found: (1) ma huang use is temporally related to stroke, myocardial infarction, and sudden death, (2) underlying heart or vascular disease is not a prerequisite for ma huang-related adverse events, and (3) the cardiovascular toxic effects associated with ma huang were not limited to massive doses. They concluded that observational and circumstantial evidence indicates that use of the substance may be associated with serious medical complications.

Boozer Daly Study – February 2002

Drs. Boozer and Daly conducted a study on the utility, safety of a combination herbal preparation consisting of ephedrine alkaloids and caffeine in weight loss. This was accepted for publication in the International Journal of Obesity (IJO), February 2002, (volume 26, page 593-604). It was a six month placebo controlled trial with a total of 167 subjects. The authors concluded that the preparation promoted body weight reduction without significant adverse events in this study. The Department of HHS and FDA have discussed this study with Drs. Boozer and Daly on two occasions. We are seeking permission to receive raw data from this study, if needed, during our ongoing review. Also, there were two editorials that accompanied this article in IJO that cautioned about the selectivity of study participants.

RAND Study -- June 14, 2002

HHS recently funded the RAND Corporation to conduct a comprehensive review of the existing science on ephedrine alkaloids, particularly those in dietary supplements. The completion of the review is targeted for the early next year. The National Institutes of Health (NIH) will use this information, which will clarify the existing state of the science on ephedrine alkaloids, to guide an expanded research effort to better understand the safety and efficacy of ephedrine alkaloids. RAND will be looking at adverse event reports, as well as published and unpublished clinical studies. This scientific review will help guide the Department and the Agency in developing future FDA regulatory actions on ephedrine alkaloids.

On a separate track, but at the same time, RAND has also been asked to conduct a dedicated review of a large number of documents from Metabolife. These include 13,000 consumer complaints and an additional 1,700 complaints with approximately 50 medical records. The completion for this review is targeted for later this year.

Metabolife Investigation – July 2002

In July 2002, FDA asked the Department of Justice (DOJ) to pursue a criminal investigation of Metabolife, to see if they had made false statements to FDA regarding the existence of adverse event reports. That investigation is ongoing at this time.

KEY FOR FDA – THE USE OF SOUND SCIENCE AND THE ABILITY TO OBTAIN NEEDED DATA

CFSAN Adverse Event Reporting System (CAERS)

Adverse events are the primary means FDA has for identifying potential safety problems with dietary supplements. Under DSHEA, FDA must rely on adverse event reports as a major component (i.e.—signal generator) of its post-market regulatory surveillance under DSHEA. Given that most experts estimate that adverse events actually reported to FDA range between 1% to 10% of actual occurrences, much time and resources have been devoted to making this system as effective as possible.

CAERS is a comprehensive computerized system that is being designed to capture and analyze all reports of consumer complaints and adverse events related to CFSAN-regulated products. This system will combine all existing Center adverse events reporting systems into one portal within CFSAN and create a state-of-the-art reporting and monitoring system that will serve as a post-marketing surveillance tool. Information gathered in CAERS will assist in the formulation and dissemination of CFSAN's post-marketing policies and procedures. Also, CAERS can provide a strong signal that is a guide toward further review of relevant scientific information.

In conjunction with the design and development of CAERS, CFSAN has developed and is currently staffing a new organizational unit within the Office of Scientific Analysis and Support. This CAERS Staff will help coordinate and facilitate the processing of adverse event reports. The staff will also help to develop mechanisms to expedite and improve timely clinical assessment of dietary supplement adverse event reports. They will serve as the core functional unit for daily operations and will work in conjunction with contractors and Program Offices to ensure a consistent and efficient workflow.

PARTNERING WITH THE FEDERAL TRADE COMMISSION (FTC) -- 1997

"Operation Cure.All"

FDA also has enhanced its cooperation with FTC, through "Operation Cure.All" and other efforts. In 1997, FTC, FDA, Health Canada, and various State Attorneys General organized and implemented an ongoing and comprehensive law enforcement and consumer education campaign against the fraudulent marketing of supplements and other health products on the Internet. The agencies have moved to stop Internet scams for supplements and other products that purport to cure cancer, HIV/AIDS, and countless other life-threatening diseases.

FDA has made Internet surveillance an enforcement priority. The Agency's partnership with FTC, and others, in "Operation Cure.All" further demonstrates FDA's commitment to monitoring illegal conduct on the Internet. Collaboration on all "Operation Cure.All" activities maximizes FDA's effectiveness in communicating to the Internet community that the various regulatory and law enforcement agencies are working together to combat health fraud. Activities are coordinated in order to ensure consistent results in areas where FTC, FDA, the States, and Health Canada have jurisdiction.

Since its inception, "Operation Cure.All" has resulted in hundreds of advisory letters directed at sites selling products with egregious claims as well as many enforcement actions directed against the marketing of fraudulent products.

The Agency has engaged in several consumer education efforts with FTC including a "Miracle Health Claims: Add a Dose of Skepticism" health fraud brochure. The brochure helps the consumer spot false and unsubstantiated claims and has suggestions on how to avoid being the target of health fraud.

Other Internet Activities – 1996-2002

As online activity has expanded over the past several years, FDA has sharpened its focus on the issue of Internet promotion, including products that are labeled as dietary supplements but are regulated as drugs because of their claims. In 1996, and again in 1999, FDA held public meetings to discuss and examine the issue of promoting, prescribing, and dispensing drugs online.

In January and February 2002, FDA and FTC participated in an International Internet search, led by the Australian Competition and Consumer Commission and with participation by 19 members of the International Marketing Supervision Network (IMSN), an organization made up of consumer protection agencies worldwide. As a result of the surf, FTC has sent over 280 advisory letters to domestic and foreign sites that were identified as making questionable claims for health-related products or services, dietary supplements. FDA is also making initial contact with Internet sites and alerting them to potential legal problems. The websites FDA visited promote dietary supplement products for treatment of diseases, including arthritis, cancer, and HIV/AIDS. CFSAN will be revisiting these sites to verify whether the website operators made corrective actions. FDA is planning follow up as appropriate. In addition, FDA and FTC are evaluating the responses to these advisory letters and they will coordinate appropriate enforcement actions if they are necessary.

In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan to expand and improve its activities in addressing the unlawful sale of drugs over the Internet. The illegally marketed drugs targeted by the plan include a variety of fraudulent products, including counterfeit drugs, drugs marketed with fraudulent health-related claims, and unapproved new drugs masquerading as dietary supplements. The elements of the plan include, among others:

- Public Outreach: FDA Talk Papers, articles in the FDA Consumer magazine, and information on FDA's website to help educate consumers about safely purchasing drugs online.
- Professional Outreach and Partnering: Periodic meetings with State and Federal regulatory and law enforcement bodies, consumers, health care practitioners, and industry to share information and strategize about how to address the challenges the Internet presents.
- Coordinating Activities with other State and Federal Agencies: Established cooperative working relationships with the Drug Enforcement Administration, the Federal Bureau of Investigation, FTC, U.S. Postal Service, U.S. Customs Service, and other appropriate Federal and State law enforcement agencies.
- International Cooperation: FDA and other Federal agencies must work with foreign governments to bring action against foreign-based sellers.

ENFORCEMENT ACTION – July 2000

When a problem arises with a product regulated by FDA, the Agency can take a number of actions to protect the public health. For dietary supplements, as with other products, the Agency initially works with the marketer of the product to correct the problem voluntarily. If that fails, the Agency also can ask the marketer to recall a product, although it cannot order a recall. The Agency can also seek, through the courts, seizure of violative products and/or an injunction against firms or individuals who market violative products, and detain or refuse entry of products presented for import at U.S. ports.

The Agency's Office of Regulatory Affairs (ORA) works in close cooperation and coordination with all of FDA's Centers in enforcing the law. With regard to health fraud specific to dietary supplements, CFSAN has the lead and is responsible for the oversight of dietary supplements. The Center for Drug Evaluation and Research also has a role to play, as many of the successful cases the Agency has brought concern products purporting to be dietary supplements that were actually drugs within the meaning of the Federal Food, Drug and Cosmetic Act and that failed to meet the regulatory requirements for drugs prior to their introduction into interstate commerce.

FDA has taken several enforcement actions pertaining to ephedra or ephedrine alkaloids. In most cases, FDA took action against these products because they

contained drug ingredients, because they were promoted to treat a disease, and/ or because they presented safety concerns. In fiscal year 2002, Congress appropriated $500,000 for dietary supplement enforcement efforts.

Nature's Nutrition Formula One – July 2000

FDA determined that this pre-DSHEA product, which was marketed between 1992 and 1994, as an all natural "nutritional supplement" that contained plant ingredients, was actually made with two pharmaceutical-grade chemicals, ephedrine hydrochloride and caffeine anhydrous. FDA received more than 100 reports of injuries and adverse reactions related to the product, ranging from serious and life-threatening conditions, such as irregular heartbeat, heart attack, stroke, seizures, hepatitis and psychosis, to more minor and temporary conditions such as dizziness, headache and gastrointestinal distress. At least one death was associated with the use of this product.

This case was developed by the alerts provided from the adverse event reports, by ORA's field staff, and by the work of FDA's Office of Criminal Investigation (OCI) with DOJ. As a result, the government launched a criminal prosecution against the company and its president.

On July 7, 2000, a Federal judge sentenced its president to 21 months in jail and fined him and his corporation $4.7 million. In his plea agreement, the company admitted it labeled Formula One as "all natural" but spiked the product with synthetic ephedrine hydrochloride and caffeine anhydrous. It also admitted that the product's labeling failed to disclose the use of the chemicals on the list of ingredients, and that he and his employees had misled FDA investigators and hindered inspections of Chemins. The sentence marked the culmination of a three-year investigation.

E'OLA International, Inc. – April 2002

At the request of FDA, U.S. Marshals seized unapproved drug products from Biogenics Inc., of St. George, Utah, doing business as E'OLA International, and at its contract manufacturer, Nature's Energy, Inc., of Pleasant Grove, Utah. About 140,000 bottles of AMP II Pro Drops valued at $2.8 million were seized, along with the bulk ephedrine hydrochloride (HCl) used in its manufacture. Although the finished products contained a drug, ephedrine HCl, they were labeled as dietary supplements for use in weight loss. The products, however, do not meet the definition of a dietary supplement because ephedrine HCl is not a dietary ingredient under the Act. FDA inspections of E'OLA revealed that the firm purchased raw materials and ephedrine HCl, directed other firms produce AMP II Pro Drops on contract, and then had them ship the finished product back to E'OLA for distribution.

Ephedrine HCl has been approved as a drug by FDA since 1948, and therefore, cannot be legally marketed as a dietary supplement. In addition, E'OLA marketed AMP II Pro Drops as a treatment for obesity. Dietary supplements cannot be marketed to treat obesity, a disease. Products marketed to treat disease are drugs. The AMP II Pro Drops were also misbranded because their labeling failed to bear adequate directions for use as is required of all drug products.

In April 2002, a United States District Court Judge signed a Consent Decree of Permanent Injunction that prohibited E'OLA from holding, manufacturing, processing, packing, labeling, promoting, or distributing AMP II Pro Drops or any similar product containing or purporting to contain ephedrine HCl or any synthetic ephedrine alkaloid. Under the decree, E'OLA was also required to destroy the seized articles at its own expense under the supervision of an HHS representative.

Additional FDA Actions

FDA is still awaiting the scientific review from the RAND study, so we can better understand the safety and efficacy of ephedrine alkaloids. In the meantime, FDA is taking the following steps:

Good Manufacturing Practices (GMPs) – October 2002

There is broad public support for dietary supplements GMPs to enhance public confidence in these products. As a preventative measure, DSHEA grants FDA explicit authority to establish GMP regulations for dietary supplements. Such regulations are critical to assuring quality, purity, and consistency in dietary supplement products. FDA has made the publication of a GMP proposed rule a high priority. After the publication, we will conduct an outreach program of the proposed rule. On Friday, October 4, 2002, the proposed rule was forwarded to Office of Management and Budget for a 90 day review.

Aggressive Enforcement of Synthetic Products

In addition to our prior efforts on synthetic ephedrine alkaloid enforcement, FDA is interested in conducting a systematic pharmacological analysis of ephedra products on the market to assess the need for further enforcement against products that contain synthetic ephedrine alkaloids.

Increased Enforcement of Illegal Ephedrine – June 14, 2002

FDA is aggressively pursuing the illegal marketing of non-herbal synthetic ephedrine alkaloid products. As part of these efforts, FDA sent six warning letters to firms unlawfully selling non-herbal ephedrine alkaloid-containing products over the Internet. Six letters went to manufacturers of products that contain the drug ephedrine or norephedrine hydrochloride labeled as dietary supplements for use in weight loss, suppression of appetite, enhanced libido, and the like. These products violate the law because they are not legal dietary supplements and are illegal drugs. Also, FDA warned another company for illegally promoting its herbal ephedra product as an alternative to street drugs.

Warning Labels

Secretary Thompson and I are very concerned about the safety of ephedra. The Secretary has requested that FDA evaluate mandatory warning labels as quickly as possible to properly alert the public regarding potential risks associated with the consumption of dietary supplements containing ephedrine alkaloids.

Yellow Jackets

Mr. Chairman, thank you for calling to Secretary Thompson's attention the death of the 16 year old boy who ingested the product, Yellow Jackets, in your letter of October 2, 2002. I have referred the matter to our enforcement personnel who have identified a distributor in the Netherlands who is making claims that are illegal under U.S. law. The website indicates that the product is intended to be used as an alternative to illicit street drugs, and is, therefore, being illegally marketed in this country. I know this comes as little comfort to the boy's family who have suffered such a tragic loss, but, yesterday, FDA issued a Cyber letter to the foreign distributor and we alerted consumers that these products present health risks. We are working closely with law enforcement officials in the Netherlands and the U.S. Customs Service to block entry of Yellow Jackets into this country by placing this product on Import Alert.

CONCLUSION

FDA will continue to work collaboratively with other governmental agencies, academia, health professionals, industry, and the Congress so that we all can be assured that we are protecting the American consumer with regard to the safety of dietary supplements. In support of that effort, the Agency firmly believes that its Dietary Supplement Strategic Plan will provide the necessary blueprint, for a comprehensive program that will implement the additional regulatory responsibilities required of FDA by DSHEA. The Agency is committed to utilizing all resources in a manner consistent with the goals and activities delineated in DSHEA in order to achieve success.

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