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News Release

FOR IMMEDIATE RELEASE
Tuesday, Dec. 30, 2003

Contact: FDA Press Office
(301) 827-6242

FDA Announces Plans to Prohibit Sales of Dietary Supplements Containing Ephedra

Consumers Advised to Stop Using Ephedra Products Immediately

HHS Secretary Tommy G. Thompson today announced that the Food and Drug Administration (FDA) has issued a consumer alert on the safety of dietary supplements containing ephedra and has notified manufacturers of its intent to publish a final rule on dietary supplements containing ephedrine alkaloids. The rule will state that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury. The rule would have the effect of banning the sale of dietary supplements containing ephedrine alkaloids when it becomes effective, 60 days following publication.

"FDA will publish a final rule as soon as possible that will formalize its conclusions that dietary supplements containing ephedrine alkaloids present unreasonable risks to those who take them for any reason," Secretary Thompson said. "Today's action puts companies on notice of our intentions, and it tells consumers that the time to stop using ephedra products is now."

"We are taking action today to notify Americans about the unreasonable risk of ephedra as currently marketed in dietary supplements," said FDA Commissioner Mark B. McClellan, M.D., Ph.D. "Our action is based on diligent and thorough work by the agency as required by the challenging legal standard in the dietary supplement law. We worked hard to obtain and review all the available evidence about the risks and benefits of ephedra, including its pharmacology, studies of ephedra's safety and effectiveness, adverse event reports, and reviews by independent experts."

"By issuing these letters today, we're sending a strong and unambiguous signal about the safety of dietary supplement products containing ephedrine alkaloids. Consumers should stop buying and using ephedra products right away, and FDA will make sure consumers are protected by removing these products from the market as soon as the rule becomes effective."

According to the Federal Food, Drug, and Cosmetic Act, a dietary supplement product is adulterated if it or a dietary ingredient within it presents a significant or unreasonable risk of illness or injury under conditions of use suggested in the labeling or under ordinary conditions of use. Under the Dietary Supplement Health and Education Act of 1994, the FDA bears the burden of proof to show that a dietary supplement presents a significant or unreasonable risk to prevent it from being marketed; in contrast, for drugs that have similar pharmacologic properties to ephedra, manufacturers bear the burden of proof of showing that the drug is safe and effective before it can be marketed.

Ephedra, also called Ma huang, is a naturally occurring substance derived from botanicals. Its principal active ingredient is ephedrine, which when chemically synthesized is regulated as a drug.

In recent years ephedra products have been extensively promoted for use to aid weight loss, enhance sports performance, and increase energy.

FDA's concerns about dietary supplements containing ephedra arise in part from ephedra's mechanism of action in the body. Ephedra is an adrenaline-like stimulant that can have potentially dangerous effects on the heart. FDA's evaluation also reflects the available studies of the health effects of ephedra. This includes many studies reviewed by the RAND Corporation, which found little evidence for effectiveness other than for short-term weight loss, as well as evidence suggesting safety risks. Other recent studies have also confirmed that ephedra use raises blood pressure and otherwise stresses the circulatory system, effects that have been conclusively linked to significant and substantial adverse health effects like heart problems and strokes.

FDA's notification reflects the agency's recent comprehensive evaluation of the science as well as a public comment period intended to cap years of debate about the risks and safety of ephedra in dietary supplements. In 1997, FDA first proposed a rule on dietary supplements containing ephedra including requiring a warning statement on these products. FDA modified this proposed rule in 2000, and last February the agency announced a series of comprehensive actions designed to protect Americans from the potentially serious risks of dietary supplements containing ephedra. To solicit comments on new evidence about ephedra as well as on a proposed warning statement, last February's actions included publishing a Federal Register notice outlining FDA's concerns and reopening the comment period.

Following publication of this notice, FDA received and reviewed tens of thousands of comments. The agency has also reviewed a comprehensive RAND Corporation report on the data on ephedra and a series of adverse event reports that it was unable to obtain more quickly because under the Dietary Supplement Health and Education Act such adverse event reports are not required to be submitted to FDA.

"We are going to issue a rule that clarifies and applies a legal standard that that has never been used before. Using the challenging standard provided under the law, we have done all we can to make sure our regulatory action will succeed," said Dr. McClellan.

FDA has sent 62 letters to firms marketing dietary supplements containing ephedra and ephedrine alkaloids alerting them of this future rule.

While working on the forthcoming rule, FDA has been actively protecting the public health through a series of high-profile enforcement actions aimed at addressing the public health danger. Dietary supplement enforcement actions include inspections that resulted in voluntary compliance, voluntary recalls, warning letters, seizures and injunctions, criminal enforcement and joint enforcement actions with the Federal Trade Commission and the Department of Justice. In conjunction with FDA's actions to date, classes of ephedra products have already been removed from the market (for example, many products marketed for enhancing sports performance), the demand for ephedra products has declined significantly, and many companies have already ceased marketing. (More detail on these actions can be found at <http://www.fda.gov/ola/2003/dietarysupplements1028.html>).

Additional materials relating to today's announcement are available online at www.fda.gov.

Additional materials:

FDA letter: <http://www.fda.gov/oc/initiatives/ephedra/december2003/warningltr.html>

List of companies receiving letter:

<http://www.fda.gov/oc/initiatives/ephedra/december2003/letterslist.html>

2/03 press release: <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00875.html>

Consumer Advisory: <http://www.fda.gov/oc/initiatives/ephedra/december2003/advisory.html>

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Questions and Answers about FDA's Actions on Ephedra Dietary Supplements

Dec. 30, 2003

What did FDA do today?

FDA issued a consumer alert on dietary supplements containing ephedrine alkaloids, as well as letters to manufacturers who market such supplements, that regulatory action to restrict sales of these products is imminent because they pose an unreasonable health risk. FDA intends to publish a final rule on ephedra in the coming weeks. The rule will provide the basis for FDA's conclusion that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use in the labeling (or if no suggested conditions than ordinary use) and are therefore adulterated under Section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

What is the purpose of the consumer alert?

To let consumers know as quickly as possible about FDA's regulatory determination, as the agency completes the administrative actions required under the dietary supplement law.

What is the purpose of the letters?

FDA is notifying manufacturers and distributors of the publication of this rule, which becomes final 60 days after publication, and advising them that, at that time, FDA may take enforcement action against them or the products if they do not cease distribution of the products.

Are you banning Ephedra?

That is, essentially, what the rule will do. The rule will conclude that dietary supplements containing ephedrine alkaloids present an unreasonable risk to the public health and are adulterated and unacceptable under Section 402(f)(1)(A) of the FD&C Act.

Why didn't FDA reach this conclusion sooner?

The law that governs how FDA can regulate dietary supplements, the Dietary Supplement Health and Education Act (DSHEA), requires FDA to do a lot of hard work with limited tools in order to determine that a dietary supplement is too unsafe to be marketed. In contrast to drugs, which must be proven safe and effective to be marketed, DSHEA requires FDA to develop evidence post marketing that a dietary supplement presents an "unreasonable risk of illness or injury." But FDA has no authority to require any studies of safety or effectiveness, or even to obtain reports of adverse events from manufacturers. FDA first proposed regulating ephedra in 1997, but commenters including the U.S. General Accounting Office generally believed that FDA had not developed sufficient evidence for action. There is now considerably more evidence available on ephedra's risks and benefits than when the proposed rule was published. Earlier this year, the Agency published a *Federal Register (FR)* notice *reopening* the comment period on its 1997 proposed rule on dietary supplements containing ephedrine alkaloids to seek comment on new scientific evidence about the risks of these products and on a proposed warning statement for the labels of these products. The *FR* announcement also sought comments on whether, in light of current information, FDA should determine that dietary supplements containing ephedrine alkaloids present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or under ordinary conditions of use if the labeling is silent. In FDA's view, "unreasonable risk" implies a risk-benefit calculus. In order to make such a calculus, the FDA had to examine the best available scientific evidence and take it into account in assessing whether the product's known or suspected risks outweigh its known or suspected benefits. We sought comment from health professionals, the supplement industry, and the general public on any additional data on ephedra's safety, so that FDA could acquire the most complete picture possible of the product's potential risks, as a basis for appropriate further regulatory action.

FDA's actions are to be reviewed under a strict judiciary standard that requires the agency to

provide as thorough of a foundation as possible for its regulatory action. This regulation will be the first time ever that the standards in the dietary supplement law, now ten years old, have been used to impose major restrictions on the sale of a dietary supplement.

What has FDA been doing to meet the requirements to take action under the dietary supplement law?

FDA has gone to great lengths to obtain and review all of the relevant scientific evidence on ephedra, as well as adverse event information, even though FDA's legal authorities to obtain this information are limited. FDA's analysis of the scientific evidence includes: a comprehensive evaluation of the scientific literature through 2002 conducted by the RAND Corporation; a review of subsequent studies including evaluation of a major study by independent academic experts; and evaluation of adverse event reports. FDA also reopened the 1997 proposed rule (see above Q&A) for comment in March 2003, in conjunction with the release of an agency "white paper" outlining the types of evidence and the legal standards that the agency was considering as a basis for further action. FDA has since received and reviewed tens of thousands of comments, and will include its formal evaluation of all of these comments in the final rule. Completing a major new rule on a never-before used legal standard with limited agency authorities and a significant burden of proof is difficult and time-consuming. FDA has worked as quickly as possible to complete the rule in a way that will stand up in court and thus will provide lasting protection for the public health. Given all of this effort, if FDA's action to protect the public health against an unreasonable risk cannot be sustained, then the dietary supplement law will clearly need to be reconsidered.

What have you been doing in the meantime to protect the public health?

While we have been preparing our forthcoming rule, we have been very active in protecting the public health through a series of high profile enforcement actions aimed at addressing a real public health danger. In conjunction with FDA's enforcement actions and other public activities involving ephedra, entire categories of ephedra products have been withdrawn from the market, and many manufacturers have withdrawn as well. Enforcement actions include inspections that resulted in voluntary compliance, voluntary recalls, warning letters, seizures and injunctions, criminal enforcement, and joint enforcement actions with FTC and DOJ. (More detail on these actions can be found at <http://www.fda.gov/ola/2003/dietarysupplements1028.html>)

Examples of prominent FDA outreach activities in this area include:

- In October 2001, FDA brought a seizure action against \$2.8 million worth of finished drug products containing synthetic ephedrine hydrochloride that were labeled as dietary supplements. United States v. 1009 Cases . . . E'ola International AMP II, No. 2:01CV - 820C (D. Utah filed Oct. 22, 2001). As a result of this seizure, in 2002, the manufacturer signed a consent decree agreeing to the condemnation and destruction of the seized products and prohibiting it from manufacturing or distributing violative ephedrine hydrochloride products. In other actions, we have sent warning letters to multiple firms that were marketing products containing synthetic ephedrine alkaloids as dietary supplements, resulting in the removal of the illegal products from the marketplace.
- On February 28, 2003, based on 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 has been marketed, the impact of these warning letters has been substantial. These products have generally complied with our letters. FDA continues to monitor them to ensure they comply with the law, and will take further enforcement actions as necessary.
- On March 31, 2003, FDA also took new enforcement action against firms marketing street drug alternative products, some of which contained ephedra or other sources of ephedrine. FDA sent warning letters to eight firms. The majority of the firms stopped selling these products or removed the street drug alternative claims for these products.

In addition to the above enforcement actions:

- On March 7, 2003, FDA announced proposed rules to establish manufacturing and labeling standards for all dietary supplements. FDA's proposed rule is intended to reduce risks associated with adulterated or misbranded dietary supplement products. FDA solicited comments from the public and industry on this proposal. Written comments were received until August 11, 2003, and FDA expects to finalize the rule in the coming year.
- FDA has also taken new steps to educate the public about dietary supplements containing ephedra. In February 2003, in proposing a warning label and possible further regulatory action for ephedra products, FDA described adverse events that have been associated with ephedra and particular risks faced by persons with certain medical conditions. The proposed label warns about an association of ephedra use with serious

adverse events, including heart attack, seizure, stroke, and death; cautions that the risk can increase with the dose, with strenuous exercise, and with other stimulants such as caffeine; specifies certain groups (such as women who are pregnant or breast feeding) who should never use these products; and lists other conditions, such as diseases and the use of certain medications, that rule out the use of ephedrine alkaloids.

Other examples of FDA's continued outreach efforts to promote the safe use of dietary supplements include:

- Expanded use of our Web site to communicate critical information and useful strategies about dietary supplements to industry and consumers. Examples include FDA Talk Papers, articles in the FDA Consumer magazine, Fact sheets, etc. Other examples of these materials include CFSAN's "Overview of Dietary Supplements" and "Tips for the Savvy Supplement User." Industry has access to guidance documents, such as FDA's "Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide" which discusses compliance with the Agency's regulations implementing DSHEA's labeling provisions.
- FDA continues to work closely with other Federal and state entities including FTC, DEA, Customs, etc. involved in combating health fraud. An example is our joint FDA/FTC project entitled, "Operation Cure-All", which is aimed at halting the Internet promotion of products, including dietary supplements, that make false or misleading disease claims. This year, FDA has issued more than five times as many warning letters for misleading and unsubstantiated claims involving dietary supplements, including misleading claims about ephedra products.

In conjunction with all of these actions, ephedra use by consumers has declined significantly, and many firms have reduced their marketing of ephedra-containing products.

Why a rule?

Because the FDA intends for ephedra-containing dietary supplements to stay off the market. A rule is the most efficient and powerful way to achieve successful enforcement. It will apply to all types of currently-marketed dietary supplements containing ephedrine alkaloids, not individual products. It will provide a far stronger foundation for sustaining FDA's regulatory action in court, because it will comprehensively lay out the scientific basis for FDA's action. In addition, this rule will, for the first time, articulate the legal standard by which we can successfully undertake and enforce the agency's actions to protect the public health under the challenging standards of DSHEA.

What types of enforcement actions are possible?

FDA has a variety of enforcement possibilities including seizure of the product, injunction against the manufacturers and distributors of such products, and criminal prosecution of violators.

Is this rule final? Why wait 60 days?

The rule as published will be a final rule. In accordance with 5 U.S.C.801-808, the rule will become effective 60 days after publication so as to allow for congressional review.

By sending out letters right now we're sending a strong and unambiguous signal that responsible retailers should stop selling these products as soon as possible and consumers should stop buying and using ephedra products right away. The 60 days has to do with the Congressional Review Act.

Why does FDA believe "Imminent Hazard" hasn't been met in this case?

In 21 CFR 2.5, Imminent Hazard is defined, in part, as: "Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held."

The "imminent hazard" is a much higher legal threshold than "unreasonable risk." While it is challenging to acquire and evaluate the scientific evidence related to ephedra under the dietary supplement act, FDA is confident that it has a clear legal basis for taking effective action to protect consumers under the "unreasonable risk" standard. FDA is much less confident that regulatory action under the "imminent hazard" standard would be successful in keeping ephedra products off the market.

When will we see publication of this rule?

In the coming weeks. It is now under review. We don't have an exact date.

How did FDA arrive at this final rule?

Through a series of actions. In 1997, FDA first proposed a rule on dietary supplements containing ephedra including a warning statement on these products. It was modified in 2000. Since publication of this proposal, new scientific evidence has come to light. To solicit comments on this new evidence as well as on a proposed warning statement, in February 2003 FDA published a *Federal Register* notice outlining FDA's concerns and reopening the comment period. The final rule comes as a result of public comments, literature review, adverse event reports, scientific studies and information sent to the docket.

What types of products are subject to the rule?

Dietary supplements that contain a source of ephedrine alkaloids, such as ephedra, Ma huang, *Sida cordifolia*, and pinellia.

Are all products containing ephedra affected?

Essentially all currently marketed dietary supplements will be affected by the rule. The rule does not pertain to traditional Chinese herbal remedies. It generally doesn't apply to products like herbal teas that are regulated as conventional foods.

What do the firms that received the letters have to do next?

They have to take steps to ensure that they will be in compliance with the law once it becomes effective. We hope that many responsible firms will stop marketing dietary supplements containing ephedra right away, as a number of companies have done already. But we want to be clear that all firms will have to comply with the new regulation. Firms fail to cease distribution of their products by the effective date of the rule will face the possibility of FDA enforcement action without further notice.

If FDA has concluded that these products are unsafe, why are they going to remain on the market after the final rule is issued?

Because this is what the dietary supplement law requires to take effective action against broad classes of products. The law places the burden on the FDA to prove that a dietary supplement creates an unreasonable risk, without requiring companies that market ephedra-containing products to provide clear evidence on their safety and effectiveness. To enforce a prohibition on the marketing of dietary supplements containing ephedra by any company, the agency can best meet this burden of proof in a way that receives the most legal deference by laying out all of the evidence supporting the regulatory actions and responses to public comment in a formal rule. Otherwise the agency's expert staff would have to justify the scientific basis for the agency's actions in multiple legal proceedings brought by individual manufacturers, having to review the evidence and public comments in each and every one of these cases, making it more likely that ephedra products would remain on the market. A final regulation permits effective action against entire classes of products, as the agency believes is necessary for ephedra-containing dietary supplements. In general, major regulations involving issues like ephedra safety that are not new cannot take effect until a minimum of 60 days after publication.

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Consumer Alert

P03-106
FOR IMMEDIATE RELEASE
December 30, 2003

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

Consumer Alert: FDA Plans Regulation Prohibiting Sale of Ephedra-Containing Dietary Supplements and Advises Consumers to Stop Using These Products

The Food and Drug Administration (FDA) is alerting the public to its forthcoming determination that dietary supplements containing ephedra present an unreasonable risk of illness or injury, and should not be consumed. The agency has notified firms manufacturing and marketing these products that it intends to issue a final rule prohibiting their sale, which will become effective 60 days after its publication.

The FDA has taken this step after conducting an exhaustive and highly resource-intensive process required under the Dietary Supplement Health and Education Act (DSHEA) of 1994 for banning a dietary supplement that presents a significant and unreasonable risk to human health.

To meet this challenging standard, the FDA gathered and thoroughly reviewed a prodigious amount of evidence about ephedra's pharmacology; clinical studies of ephedra's safety and effectiveness; newly available adverse events reports; the published literature; and a seminal report by the RAND Corporation, an independent scientific institute. The FDA also reviewed tens of thousands of public comments on the agency's request in February, 2003 for information about ephedra-associated health risks.

The totality of the available data showed little evidence of ephedra's effectiveness except for short-term weight loss, while confirming that the substance raises blood pressure and otherwise stresses the circulatory system. These reactions have been conclusively linked to significant adverse health outcomes, including heart ailments and strokes.

By informing more than 60 dietary supplement firms about the upcoming final rule, FDA is sending a strong and unambiguous signal that dietary supplements containing ephedrine alkaloids present an unreasonable risk. Consumers are urged to stop buying and using these products immediately.

Ephedra, also called Ma Huang, is a naturally occurring substance derived from botanicals. Its principal active ingredient is ephedrine, which when chemically synthesized is regulated under the Federal Food, Drug and Cosmetic Act of 1938 as a drug. In contrast to the DSHEA-regulated dietary supplements that contain natural ephedra, the safety and effectiveness of the synthesized ephedrine has to be proven by the manufacturer, not the FDA. In recent years ephedra products have been extensively promoted for aiding weight control and boosting sports performance and energy.

Today's announcement is a continuation of a process that started in June, 1997 when FDA first proposed to require a statement on dietary supplements with ephedra warning that they are hazardous and should not be used for more than 7 days. FDA modified this proposed rule in 2000, and in February 2003 it announced a series of measures that included strong enforcement actions against firms making unsubstantiated claims for their ephedra-containing products.

These measures have prompted voluntary compliance with FDA rules, voluntary product recalls, FDA warning letters, seizures and injunctions, criminal actions, and joint enforcement actions with the Federal Trade Commission and the Department of Justice. (More detail on these actions can be found at http://www.fda.gov/ola/2003/dietarysupplements_1028.html). As a result, ephedra-containing dietary supplements advertised for enhanced sport performance have been removed from the market, there has been a significant decline in the demand for ephedra products, and many firms have stopped their marketing.

This letter is representative of the letters that were sent by FDA Dec. 30, 2003, to [companies marketing ephedra dietary supplements](#).



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, Maryland
20740

December 30, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

[name]
[address]

Dear Sir or Madam:

This letter concerns your product [PRODUCT NAME], which appears to be marketed as a dietary supplement. The product labeling indicates [NAME OF BOTANICAL], a botanical source of ephedrine alkaloids, as an ingredient.

FDA intends to publish a rule in the coming weeks that finds that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling of the product, or, if no conditions of use are suggested in the labeling, under ordinary conditions of use, and are therefore adulterated under Section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the Act). This rule will become effective 60 days after publication so as to allow for congressional review in accordance with 5 U.S.C. 801-808. You can find the Act and its implementing regulations through links on FDA's Internet home page at www.fda.gov.

The preamble to the rule will contain a detailed explanation of the agency's basis for its determination. The purpose of this letter is to give you advance notice of the publication of this rule to facilitate your earliest compliance. FDA intends to begin enforcing the rule as soon as it becomes effective.

Sincerely yours,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

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Companies Marketing Ephedra Dietary Supplements that Received FDA's Letter Dec. 30, 2003.

Advanced Nutrient Science International
10540 72nd St
Largo, FL 33777

Advanced Pharmaceutical Research
732 Circle Drive
Aberdeen, SD 57401

Advanced Scientific Nutrition
1813 Cascade Ave
Hood River, OR 97031

AFS Labs/S&K Labs
2637 East Atlantic Blvd
Pompano Beach, FL 33062-4939

Alpha Pharmaceuticals, Inc.
3225 S. McLeod Drive, Suite 100
Las Vegas, NV 89121

Alternative Pharmaceuticals/Lion Products
400 3rd St
Red Oak, IA 51566

AST Sports Science
120 Capital Drive
Golden, CO 80401

Betastatin Nutritional Research, LLC
1187 Washington St
Toms River, NJ 08753

California Advanced Laboratories
96 Inverness Dr. East, Suite R
Englewood, CA 80112

Carter Reed

Competition Nutrition
11 Bowman Lane
Commack, NY 11725

Cytodyne Technologies
2231 Landmark Place
Manasquan, NJ 08736

D & A Nutrition, Inc.
2017 West Pensacola St
Tallahassee, FL 32304

D&E Pharmaceuticals, Inc.
206 Macopin Rd
Bloomingdale, NJ 07403

Dymatize Nutrition

3200 Commander, Suite 110
Carrollton, TX 75006

EAS
555 Corporate Circle
Golden, CO 80401

Elation Therapy
2912 Perrington Way
Marietta, GA 30066

Envision Research
2275 Huntington Drive, #405
San Marino, CA 91108

Extreme Labs
4440 S. Maryland Pkwy, Suite 208a
Las Vegas, NV 89119

Genna Pharm, Inc.
110 Woodland Trl
Leander, TX 78641

German American Technologies
123 Downs Ave
Stamford, CT 06902

Higher Power
361 Steelhead Way
Boise, ID 83704

Hi-Tech Pharmaceuticals
5875 Jimmy Carter Blvd Suite 720
Norcross, GA 30071-2955

IDS Sports
572 S. Econ Circle, Suite 120
Oviedo, FL 32765

Kaizen, Inc.
11944 South La Cienega Blvd
Los Angeles, CA 90250

Klein Laboratories
47 Capital Drive
Wallingford, CT 06492

Klein-Becker USA/Basic Research
5742 W. Harold Gatty Drive
Salt Lake City, UT 84116

Mass Quantities
1010 Northern Blvd, Suite 208
Great Neck, NY 11021

Maximum Nutrients
2005 South Division Ave
Grand Rapids, MI 49507

MaxLabs
9189-A Winkler Dr.
Houston, TX 77017

MaxOut BODY
2717 W. Cypress Creek Road
Ft. Lauderdale, FL 33309

Metabolife International
5643 Copley Drive

San Diego, CA 92111

Metabolite Rx

Nature's Nutrition, Inc.
901 Wildwood Trail
Big Sandy, TX 75755

Nutraceutical Corp.
1400 Kearns Blvd
Park City, UT 84060

Nutraceuticals
8 Ridgedale Ave
Cedar Knolls, NJ 07927

Nutrex Research, Inc.
11007 Creighton Drive
Orlando, FL 32817

NVE Pharmaceuticals
33 Newton-Sparta Road
Newton, NJ 07860

Optimum Nutrition Inc.
12424 NW 39th St
Coral Springs, FL 33065

Peak Nutrition, Inc.
1097 11th St., P.O. Box 87
Syracuse, NE 68446

Performance Biomedical Laboratories
1805 Eastern Ave
Baltimore, MD 21231

Pure Performance Nutrition, Inc.
4811 East La Palma Ave
Anaheim, CA 92807

Rexall Sundown/Worldwide Sport Nutrition
6111 Broken Sound Pkwy, NW
Boca Raton, FL 33487

S.A.N. Corp
716 N. Ventura Rd., #431
Oxnard, CA 93030

Schwartz Laboratories
6905 Plainfield Rd
Cincinnati, OH 45236

Scientific Fitness
140 Pennsylvania Ave
Oakmont, PA 15139

Scitrex
1187 Coast Village Rd., PMB 478
Santa Barbara, CA 93108

Silver Sage
5742 W. Harold Gatty Drive
Salt Lake City, UT 84116

SlimSense
9053 Harlan St., Suite 30
Westminster, CO 80031

Southern Pharmaceuticals
2190 NW 89th Place
Miami, FL 33172

Sports Nutrition 2000
113 Knollwood Dr., Suite 425
Cherry Hill, NJ 08002

Sports Nutrition International
78 Iowa St.
Paterson, NJ 07505

Sports One
47 Capital Drive
Wallingford, CT 06492

Supplement Research & Advancements (SRA)
1930 Village Center Circle, #3-405
Las Vegas, NV 89134

TSN Labs
6146 South 350 West Suite A1
Murray, UT 84107

TwinLab
150 Motor Parkway
Hauppauge, NY 11788

Ultimate Nutrition
21 Hyde Rd
Farmington, CT 06034-0643

Universal Nutrition
3 Terminal Road
New Brunswick, NJ 08901

Urban Biologics
494 Riverview Drive
Totowa, NJ 07512

VitaLIFE
1 Scarborough Station Plaza
Scarborough, NY 10510-0806

VPX/Vital Pharmaceuticals
6573 Stirling Road
Ft. Lauderdale, FL 33314

Wellness International Network
5800 Democracy Drive
Plano, TX 75024

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