

LAW OFFICES

# HYMAN, PHELPS & McNAMARA, P. C.

700 THIRTEENTH STREET, N. W.  
SUITE 1200  
WASHINGTON, D. C. 20005

TELEPHONE  
(202) 737-5600  
FACSIMILE  
(202) 737-9329  
DIRECT DIAL  
(202) 737-4289

HYMAN, PHELPS & McNAMARA  
2603 MAIN STREET  
SUITE 650  
IRVINE, CALIFORNIA 92614  
TELEPHONE (714) 553-7400  
FACSIMILE (714) 553-7433

ALAN M. KIRSCHENBAUM  
DOUGLAS B. FARQUHAR  
OF COUNSEL

ROBERT T. ANGAROLA  
(1945-1996)

JAMES R. PHELPS  
PAUL M. HYMAN  
ROBERT A. DORMER  
STEPHEN H. McNAMARA  
ROGER C. THIES  
THOMAS SCARLETT  
JEFFREY N. GIBBS  
BRIAN J. DONATO  
FRANK J. SASINOWSKI  
DIANE B. MCCOLL  
A. WES SIEGNER, JR.  
SAMIA N. RODRIGUEZ  
MARY BETH NERAAS  
JUDITH E. BEACH  
JENNIFER B. DAVIS  
JOHN A. GILBERT, JR.  
FRANCES K. WU  
DAVID B. CLISSOLD  
KATE DUFFY MAZAN  
HOLLY M. BAYNE\*

\*NOT ADMITTED IN DC

April 17, 1998

0927 '98 APR 17 P1:00

### BY HAND DELIVERY

Dockets Management Branch  
Food and Drug Administration  
12420 Parklawn Drive  
Room 1-23, HFA-305  
Rockville, Maryland 20857

Re: FDA Notice Titled "International Drug Scheduling;  
Convention and Psychotropic Substances;  
Dihydroetorphine; Ephedrine; Remifentanil; Isomers of  
Psychotropic Substances," Docket No. 98N-0148

To Whom It May Concern:

The following are the comments of Starlight International Ltd. and Nutraceutical Corporation (Starlight and Nutraceutical) concerning the above-referenced notice. Based on the following information, Starlight and Nutraceutical maintain that dietary supplements containing ingredients including less than 25 mg of ephedrine alkaloids per serving should be exempt from any international control of the drug ephedrine.

### BACKGROUND

Starlight and Nutraceutical are committed to the responsible marketing of safe and useful dietary supplement products. Starlight and Nutraceutical market combination dietary supplement products that include extracts of the herb *Ephedra* at safe levels, below 25 mg of ephedrine alkaloids per serving. Starlight and Nutraceutical actively oppose the marketing of any dietary supplements for euphoria, including products containing *Ephedra*. Starlight and Nutraceutical believe that such products are illegal drugs, not legal dietary supplements, under the Federal Food, Drug, and Cosmetic Act, as FDA has maintained in

98N-0148'

C8

warning letters sent to a number of companies marketing these products. See attached warning letters, Tab 1. Current law, if enforced by FDA, is sufficient to remove from the market illegal drugs masquerading as dietary supplements and marketed to minors for euphoria.

Other than the illegal products marketed for euphoria, dietary supplements containing ephedrine alkaloids are widely and safely consumed by consumers in the United States in millions of doses per year for weight management and other purposes. Starlight and Nutraceutical are not aware of information establishing that legally marketed dietary supplements containing ephedrine alkaloids are subject to abuse.

Further, dietary supplements containing low levels of ephedrine alkaloids found in the herb *Ephedra* are not useful as precursor products to manufacture methamphetamine. Available methods used by clandestine laboratories in the United States to manufacture methamphetamine from readily obtainable over-the-counter drug preparations containing ephedrine and pseudoephedrine **do not yield any methamphetamine** when their methods are applied to combination dietary supplement products containing ephedrine alkaloids. See attached statement of laboratory investigation, Tab 2. In addition, the Drug Enforcement Administration (DEA) has reported only one laboratory seizure in the last three years in which "*Ephedra* tablets" were seized. (It is not clear from the DEA report whether "*Ephedra* tablets" meant combination dietary supplements containing ephedrine alkaloids extracted from the herb *Ephedra*, or whether the tablets were made from the *Ephedra* plant material itself.)

The lack of documented use of dietary supplements to make methamphetamine, the lack of evidence to show that recipes for making methamphetamine from dietary supplements of *Ephedra* even exist, either through the Internet, law enforcement channels or any other informational sources, and the attached laboratory analysis showing that these products are not useful for making methamphetamine all lead to the conclusion that any controls over the drug ephedrine should not include dietary supplements containing small amounts of ephedrine alkaloids.

#### RESPONSE TO QUESTIONNAIRE

Starlight and Nutraceutical provide the following responses to the World Health Organization's (WHO's) questionnaire.

**Question 1: "Availability of the substance (registered, marketed, dispensed, etc.)."**

Dietary supplements combining ephedrine alkaloids with other dietary ingredients are legally marketed in the United States

through retail stores and through direct sales or network marketing. These products are, therefore, readily available to almost all consumers.

**Question 2: "Extent of abuse of the substance."**

Products masquerading as dietary supplements but illegally marketed for euphoria have been abused. However, Starlight and Nutraceutical expect that such products have been or will be removed from the market as a consequence of FDA enforcement actions. Starlight and Nutraceutical are not aware of any information establishing the abuse of legally marketed dietary supplements containing a combination of ingredients including ephedrine alkaloids.

**Question 3: "Degree of seriousness of public health and social problems associated with abuse of the substance."**

Starlight and Nutraceutical are unaware of any information establishing that legally marketed dietary supplements combining dietary ingredients including ephedrine alkaloids at or below the level of 25 mg of ephedrine alkaloids per serving have resulted in the type of public health and social problems listed in the WHO questionnaire, that is, "acute intoxication, accidents, work absenteeism, mortality, behavioral problems, criminality, etc."

**Question 4: "Number of seizures of the substance in illicit traffic during the previous three years and the quantities involved."**

As reported by DEA, Starlight and Nutraceutical are aware of only one seizure potentially involving dietary supplements containing a combination of dietary ingredients including ephedrine alkaloids. This case likely represents only experimental use. Laboratory analysis indicates that established methods for making methamphetamine from ephedrine, when applied to dietary supplements, do not yield methamphetamine and are therefore not useful.

**Question 5: "Identification of the seized substance as of local or foreign manufacture and indication of any commercial markings."**

Starlight and Nutraceutical are not aware of any such documented seizures for dietary supplements containing a combination of dietary ingredients including ephedrine alkaloids.

**Question 6: "Existence of clandestine laboratories  
manufacturing the substance."**

There is no evidence that clandestine laboratories are using dietary supplements containing a combination of dietary ingredients including ephedrine alkaloids to make methamphetamine. Moreover, the attached laboratory analysis shows that such dietary supplements are not useful in making methamphetamine.

**ECONOMIC IMPACT**

In the event that dietary supplements containing Ephedra are not exempt from potential international controls recommended by WHO for ephedrine, the economic impact on the U.S. economy would be significant. Starlight and Nutraceutical estimate that, at the network marketing level alone, there are several hundred thousand distributors handling dietary supplements containing a combination of ingredients, including low levels of ephedrine alkaloids. The imposition of regulatory controls in the form of registration, reporting and recordkeeping requirements for such finished dietary supplements would essentially curtail the distribution of these products, causing a significant loss of income to hundreds of thousands of families and individuals. In fact, FDA estimates the potential cost of a DEA regulation regarding dietary supplements containing ephedrine alkaloids as chemical mixtures to be \$100,000,000, if network marketing distributors are not exempt from the proposal. Starlight and Nutraceutical estimate the figure to be several times that amount.

**CONCLUSIONS**

Current information shows that dietary supplements containing a combination of dietary ingredients including ephedrine alkaloids are not useful to make, and are not being used to make, methamphetamine. Therefore, even though these products do contain relatively small amounts of the chemical ephedrine, dietary supplements should be exempt from any controls recommended by WHO for ephedrine.

Sincerely,

*A. Wes Siegner, Jr.*  
A. Wes Siegner, Jr. *by*  
*Amb*

AWS/HMB/cld  
Attachments



**WARNING LETTER**

AUG 29 1997

Mr. Sean S. Shayan  
Global World Media Corp.  
1501 South Main Street, Unit #203  
Venice, California 90292

Ref: No. 97-HFD-310-02

Dear Mr. Shayan:

This letter notifies you that your drug product, "herbal ecstasy™," is in violation of the Federal Food, Drug, and Cosmetic Act (the FDCA). The product is labeled as containing Tibetan Ma Huang, wild Brazilian guarana, Chinese black ginseng, wild ginko biloba, African raw kola nut, gotu-kola, pho-ti-tieng, green tea extract, and rou gui (a rare form of Chinese nutmeg).

"herbal ecstasy™" is identified in promotional material as "Soar into ecstasy . . . The world's most advanced designer nutritional supplement herbal ecstasy™ is more than just another smart drug. it is a carefully formulated and thoroughly tested organic alternative . . . A fantastically light headed, tingly happy, happy buzz with no side effects . . . The effects of herbal ecstasy™ beyond smart drug capacity include: euphoric stimulation . . . high increased energy levels . . . enhanced sensory processing . . . mood elevation." These street drug alternative claims, and the use of the name "herbal ecstasy™," do not fall within the scope of claims permitted for dietary supplements.

As labeled, "herbal ecstasy™" is a drug as described in §201(g) of the FDCA and a "new drug" as described in §201(p) of the FDCA which may not be legally marketed in the United States without an approved New Drug Application. In addition, it is misbranded as described in §502(f)(1) of the FDCA because its labeling fails to bear adequate directions for the uses for which it is being promoted.

The claims and name indicate that "herbal ecstasy™" is offered for abuse and misuse purposes. As such, there is no legitimate drug use for this product and its continued marketing is illegal.

We request you take prompt action to correct these violations. Failure to promptly correct them may result in enforcement action being initiated by the Food and Drug Administration without further notice. The FDCA provides for seizure of illegal products (§304) and for injunction (§302) against the manufacture and/or distribution of illegal products.

Page 2 - Sean S. Shayan

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations.

Your reply should be sent to the Division of Labeling and Nonprescription Drug Compliance, HFD-310, Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bradford W. Williams", with a long horizontal line extending to the right.

Bradford W. Williams  
Director  
Division of Labeling and Nonprescription  
Drug Compliance  
Office of Compliance  
Center for Drug Evaluation and Research



AUG 29 1997

**WARNING LETTER**

Mr. Robert Hillard  
International Oddities  
4731 Clark Avenue  
Long Beach, California 90808

Ref. No: 97-HFD-310-03

Dear Mr. Hillard:

This letter notifies you that your drug product, "Herbal Advanced Formula Hextasy," is in violation of the Federal Food, Drug, and Cosmetic Act (the FDCA). The product is labeled as containing "A superior, synergistically re-synthesized herbal supplement Ingredients - Muira Pauma, Ma Huang, Fo-Ti, Guarana, Catuba, Cola Nut, Ginko Biloba, Rou Gui, Chinese Green Tea, Suma, Gotu Cola, Ginseng."

"Herbal Advanced Formula Hextasy" is identified in promotional material as "Absolutely the BEST of all the extacy alternatives (Guaranteed) . . . But none have the Super Happy Feelings, Cerebral Sensory Expansion, Extreme Euphoria, Mood Elevation, Tingling & Sexual Sensations of Hextasy!! 'Effects came on immediately - lasted 5 hours with no burn out. Amazing' 'You've done it - Pure euphoric joy in a pill. Thanks' 'Legal or not - this is the greatest thing I've tried in a long time.'" These street drug alternative claims, and the use of the name "Herbal Advanced Formula Hextasy" do not fall within the scope of claims permitted for dietary supplements.

As labeled, "Herbal Advanced Formula Hextasy" is a drug as described in §201(g) of the FDCA and a "new drug" as described in §201(p) which may not be legally marketed in the United States without an approved New Drug Application (NDA). In addition, it is misbranded as described in §502(f)(1) of the FDCA because its labeling fails to bear adequate directions for the uses for which it is being promoted.

The claims and name indicate that "Herbal Advanced Formula Hextasy" is offered for abuse and misuse purposes. As such, there is no legitimate drug use for this product and its continued marketing is illegal.

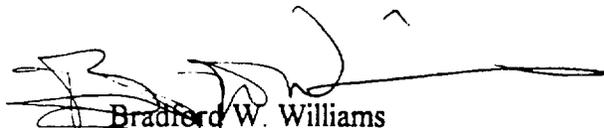
We request you take prompt action to correct these violations. Failure to promptly correct them may result in enforcement action being initiated by the Food and Drug Administration without further notice. The FDCA provides for seizure of illegal products (§304) and for injunction (§302) against the manufacture and/or distribution of illegal products.

Page 2 - Robert Hillard

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations.

Your reply should be sent to the Division of Labeling and Nonprescription Drug Compliance, HFD-310, Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bradford W. Williams", is written over a horizontal line. The signature is somewhat stylized and overlaps the text below it.

Bradford W. Williams  
Director  
Division of Labeling and Nonprescription  
Drug Compliance  
Office of Compliance  
Center for Drug Evaluation and Research



AUG 29 1997

**WARNING LETTER**

Mr. Perry Hitt  
Hit Products, Incorporated  
c/o Riverdale Tobacco Shop  
6725 44th Avenue  
Hyattsville, Maryland 20782

Ref. No: 97-HFD-310-04

Dear Mr. Hitt:

This letter notifies you that your drug product, "X TABLETS," is in violation of the Federal Food, Drug, and Cosmetic Act (the FDCA). The product is labeled as containing "High potency concentrates of fresh ginko biloba, siberian wuchaseng, spirulina, South American guarana, and Ma Huang."

"X TABLETS" are identified in promotional material as "The World's most powerful ecstasy alternative," "Pleasurable stimulation of the senses... a real body and cerebral experience," "Tingling sensations, positive vibes, & powerful rush..." These street drug alternative claims, and the use of the name "X TABLETS," do not fall within the scope of claims permitted for dietary supplements.

As labeled, "X TABLETS" is a drug as described in §201(g) of the FDCA and a "new drug" as described in §201(p) which may not be legally marketed in the United States without an approved New Drug Application. In addition, it is misbranded as described in §502(f)(1) of the FDCA because its labeling fails to bear adequate directions for the uses for which it is being promoted.

The claims and name indicate that "X TABLETS" is offered for abuse and misuse purposes. As such, there is no legitimate drug use for this product and its continued marketing is illegal.

We request you take prompt action to correct these violations. Failure to promptly correct them may result in enforcement action being initiated by the Food and Drug Administration without further notice. The FDCA provides for seizure of illegal products (§304) and for injunction (§302) against the manufacture and/or distribution of illegal products.

Page 2 - Perry Hitt

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations.

Your reply should be sent to the Division of Labeling and Nonprescription Drug Compliance, HFD-310, Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bradford W. Williams', with a long horizontal flourish extending to the right.

Bradford W. Williams

Director

Division of Labeling and Nonprescription  
Drug Compliance

Office of Compliance

Center for Drug Evaluation and Research



**WARNING LETTER**

AUG 29 1997

Mr. Murray Moss and Mr. Howard Schwarz, Owners  
Spectrum Group, LLC  
226 South Beverly Drive, 2nd Floor  
Beverly Hills, California 90212

Ref. No: 97-HFD-310-05

Gentlemen:

This letter notifies you that your drug product, "e-LUDES," is in violation of the Federal Food, Drug, and Cosmetic Act (the FDCA). The product is labeled as containing "a synergistic blend of Kava Kava, Guarana, Grape Seed, Uva Ursi, Corn Silk, Cascara Sagrada."

"e-LUDES" is identified in promotional material as "Get tranquil! Get Happy! Get e-LUDES! An all-natural euphoric experience that's a safe alternative to the designer drugs of the '90's and the "LUDES" of the '70's. Created for a world gone mad, e-LUDES will make your world spin slower and help your mind unwind. Achieve euphoria without a chemical high. Nourish your mind and mellow 'tude. GET DOWN with e-LUDES!" These street drug alternative claims, and the use of the term "e-LUDES," do not fall within the scope of claims permitted for dietary supplements.

As labeled, "e-LUDES" is a drug as described in §201(g) of the FDCA and a "new drug" as described in §201(p) of the FDCA which may not be legally marketed in the United States without an approved New Drug Application (NDA). In addition, it is misbranded as described in §502(f)(1) of the FDCA because its labeling fails to bear adequate directions for the uses for which it is being promoted.

The claims and name indicate that "e-LUDES" is offered for abuse and misuse purposes. As such, there is no legitimate drug use for this product and its continued marketing is illegal.

We request you take prompt action to correct these violations. Failure to promptly correct them may result in enforcement action being initiated by the Food and Drug Administration without further notice. The FDCA provides for seizure of illegal products (§304) and for injunction (§302) against the manufacture and/or distribution of illegal products.

Page 2 - Murray Moss and Howard Schwarz

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations.

Your reply should be sent to the Division of Labeling and Nonprescription Drug Compliance, HFD-310, Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bradford W. Williams", written over a horizontal line.

**Bradford W. Williams**  
Director  
Division of Labeling and Nonprescription  
Drug Compliance  
Office of Compliance  
Center for Drug Evaluation and Research



**CLIENT:** Metabolife International Inc.  
5070 Santa Fe Street  
San Diego, CA 92109

**Attn:** Mike Ellis

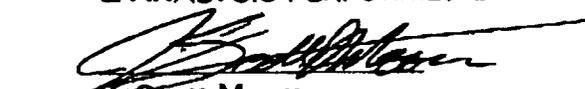
**SAMPLES:** One case of Metabolife Dietary Supplement 356 was received March 23, 1998. The label listing the ingredients in this product is attached.

**TESTS:** It was requested that we attempt to produce methamphetamines from the Metabolife Dietary Supplement using the "street" method published in The Journal of Forensic Sciences, Vol. 40, No. 4, July 1995.

**RESULTS:** The tablets were initially analyzed for ephedra content by High Performance Liquid Chromatography (HPLC). Each tablet was found to contain 13.1 mg/tablet on average of ephedra alkaloids. The contents of the 12 bottles of Metabolife Dietary Supplement 356 were ground resulting in approximately 1.3 kg of starting material (13.7 g ephedra alkaloids). The material was extracted into methanol and the extract was reacted with red phosphorus and hydriodic acid for five hours. The resulting mixture was basified and extracted into freon. The freon was then acidified using hydrogen chloride gas. This should have resulted in the production of methamphetamine crystals, however it formed a black tar like material. The material was tested by Gas Chromatography/Mass Spectroscopy (GC/MS) and found to contain mostly ephedra alkaloids and caffeine, the presence of methamphetamine was not detected.

**CONCLUSION:** The procedure described above was performed according to the method published in The Journal of Forensic Sciences, Vol. 40, No 4, July 1995, titled "Ephedra's Role As a Precursor in the Clandestine Manufacture of Methamphetamine" by K.M. Andrews. Based on our analysis, it does not appear that this published method can be used to make methamphetamine from Metabolife's Dietary Supplement 356.

**REPORT WRITTEN  
& ANALYSIS PERFORMED BY:**

  
J. Scott Moore  
Technician III

**REPORT REVIEWED BY:**

  
Nicole M. Enderle  
Chemist

This report applies only to the sample, or samples, investigated and is not necessarily indicative of the quality or condition of apparently identical or similar products. As a mutual protection to clients, the public and these Laboratories, this report is submitted and accepted for the exclusive use of the client to whom it is addressed and upon the condition that it is not to be used, in whole or in part, in any advertising or publicity matter without prior written authorization from Hauser Laboratories. This report may be copied only in its entirety.