



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g-4104d

MAR 31 2003

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

VIA FEDERAL EXPRESS

Owner/President
Ecstasy Melrose
7217 Melrose Avenue
Los Angeles, California 90046-7619

Ref. No: 03-HFD-312-02

Dear Sir or Madam:

This letter is written in reference to your firm's marketing of various products that are promoted on your Internet web site, www.ecstacymelrose.com, as alternatives to illicit street drugs. Some of these products purport to contain sources of ephedrine (i.e., ephedra, ma huang, or sida cordifolia).

Your Internet web site, from which these products may be ordered, promotes these products with brand names and claims, indicating that they are intended to be used as street drug alternatives, and lists ingredients of these products, as follows:

- **Ecstasy RX 3 tablets**

"These new powerful and exciting pills are great for partying and nighttime [sic]! They take you back to the original 'ecstasy' experience, WITH mushrooms! 750 Mg. strong blue tablets, which contain: 100% natural extracts of Sida Cordifolia [sic], Paulinia Cupana, Panax Ginseng, Ginko Biloba L., 'Fly Agaric' Amanita Muscaria mushrooms, B-6, and B-12 vitamins. Love & Light!"

- **Original Herbal Ecstasy tablets**

"Active Ingredients: 100% natural vegetarian: Tibetan ephedra, Brazilian Pauline cupana, black pans ginseng, German ginko biloba, African colacuminata, Indonesian centella Asiatic, polygonum multeflorum, camellia sinensis, myristica fragrans, love and light . . . Synergistically blended to insure visionary vibration."

- **Ek-sta-sis tablets**

"There was no sound. Just an enveloping sense of being present at the cusp of creation. ek-sta-sis – the original form of the word ecstasy. In Greek it originally

referred to the separation of the soul from the body. . . . One of the most powerful product [sic]!

Active ingredients: powerful plant allies – sida cordifolia [sic]- . . . maytenus krukorii, L-Tyrosine and Niacin.”

- **Liquid Ecstasy**

“A new kind of pleasure beyond just herbs, a powerful, fast working drink. . . . Active ingredients: powerful plant allies – sida cordifolia [sic] . . . maytenus krukorii . . .”

- **Organic Ecstasy**

“With . . . Soma ‘Fly Agaric’ Mushrooms Can sex get any better? . . . Enhance it with 7th Heaven . . . Ingredients: Sida Cordifolia Extract, Yerba Mate Extract, Guarana Extract, Green Tea Extract, Gotu Kola Extract, Wild Oat Extract, Wild Yam Extract, Cat’s Claw Extract, Chromium Picolinate, and Essence Of Amanita Mushrooms ‘Fly Argaric’”

- **Ecstasy Sex**

“Enhance it with 7th Heaven A feeling of elevated happiness . . . The effect is an amazing full body stimulation. . . . focuses on sensuality and intimate touching.”

- **7th Heaven tablets**

“The original herbal enhancer . . . Active ingredients: Pure Chinese Ephedra Sinica Extract, Brazilian Guarana (Paulina cupana), Love and Light.”

7th Heaven is promoted for use to “enhance” other street drug alternative products sold on your web site such as Original Herbal Ecstasy, Ek-sta-sis, Liquid Ecstasy, Organic Ecstasy, and Ecstasy Rush.

- **Ecstasy Rush tablets**

“*A feeling of happiness *Tingly skin sensations – enhance senses of touch, sight, and sound. . . . This is our new formulation of Herbal Ecstasy containing the herb Kava Kava. Ecstasy Rush is powerful giving full body stimulation. Ecstasy Rush focuses primarily on energy.”

- **Herbal Pure Ecstasy tablets**

"The original Ecstasy has the herb Ma Huang, which contains ephedra. This new formulation is our Pure Herbal Ecstasy containing the herb Kava Kava. This provides an alternative for those who may not be able to use ephedra. The experience is still a powerfully amazing, full body stimulation."

- **Ecstasy Tripadelic tablets**

"The name says all Highly Tripadelic"

- **Phantastica snuff**

"Herbal Shamanic Snuff . . . Contains: Rare high potency extracts of Ephedra sinica (naturally occurring from plant sources) and paulina cupana."

- **Eecstasy [sic] Happy tablets**

"Does Happiness come in a pill? Find out, Get Happy"

- **Dream Drop tablets**

"Dream Psychedelic From the dawn of time, ancient and mystical civilizations have used various sacred herbs in order to induce visions while asleep. Active Ingredients: Damiana (Tumera Diffusa), Kava Kava (Piper Methysticum), Valerian (Valerian Officinalis)."

- **Trance tablets**

"These mystics also believed that proper meditation and nutrition are intricate to a trance state. A rare extract of the magical botanical Skullcap has been specially selected to maximize a nutritional balance and induce a visionary trance."

FDA is aware that some street drug alternatives are being marketed as dietary supplements. FDA does not believe that street drug alternatives are intended to be used to augment the diet to promote health or reduce the risk of disease. Accordingly, street drug alternatives are not intended to supplement the diet and are not dietary supplements. Further, a product's method of intake can preclude it from being a dietary supplement. In March of 2000, FDA made available a guidance for industry on street drug alternatives. This document contains additional information and is available at <http://www.fda.gov/cder/guidance/index.htm>.

Based on the claims cited, the products discussed above are "drugs" as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Moreover, they are also "new drugs" (Section 201(p) of the Act) because there is no evidence that these products are generally recognized as safe and effective for their intended uses. Under Section 505 of the Act, a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Since these products are not the subjects of approved NDAs, they may not be marketed in the United States and their continued marketing violates Section 505 of the Act.

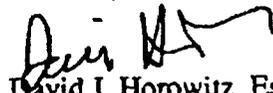
This letter is not intended to be an all-inclusive review of your Internet web site or all of your firm's labeling and products, and it is not intended to be an all-inclusive list of violations concerning your firm and its products. You are responsible for ensuring that all products marketed by your firm are in compliance with applicable United States laws.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

You must notify this office in writing within fifteen (15) working days of your receipt of this letter as to the specific actions you have taken to correct the stated violations. You should also include an explanation of each step you have taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made. Further, if your firm does not manufacture the product, your reply should also include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturing firm.

Address your reply to the Food and Drug Administration, Division of New Drugs and Labeling Compliance, 5600 Fishers Lane, (HFD-310 / MM2 / Rm. 328), Rockville, MD 20857, Attention: Dr. Linda Silvers.

Sincerely,



David J. Horowitz, Esq.

Director

Office of Compliance

Center for Drug Evaluation and Research