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Food and Drug Administration  
Rockville MD 20857

MAR 31 2003

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Jason Pacey  
1012 W. Willcox  
Peoria, Illinois 61604

Ref. No: 03-HFD-312-05

Dear Mr. Pacey:

This letter is written in reference to your firm's marketing of various products that are promoted on your Internet web site, [www.natureshighs.com](http://www.natureshighs.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.

The opening text of your web site bears the following statements:

"The Ultimate Legal High... Just because these products are 'legal' don't think that it means that they don't work. We've tried every single one and we only sell products that we have tested and got stoned on ourselves. These are all are [sic] natural herbal products which contain ingredients which have some how managed to slip through the drug classification net - they are legal and they do work!"

The following products are offered for sale on your web site:

**MOOD ENHANCERS**

• **Ek-Sta-Sis tablets**

"ek-sta-sis is a powerful replacement for Herbal Ecstasy... ek-sta-sis is more than just another smart drug. ek-sta-sis is a carefully formulated and thoroughly tested organic alternative... ek-sta-sis is the world's leading herbal euphoric stimulant... Effects may be felt from 45 to 90 min. after ingestion, and may last about 6 to 8 hours."

“Ingredients: Tibetan Ma Huang, Wild Brazilian Guarana, Chinese Black Ginseng, German Wild Ginko Biloba, African Raw Cola Nut, Russian Gotu-Kola, Indonesian Wild Fo-Ti-Tieng, Chinese Green Extract, Rou Gui (Rare form of Chinese Nutmeg).”

- **Trip2Night capsules**

“This is the best MDMA Ecstasy alternative barnone [sic], and also holds its own as a pretty good LSD alternative and antidepressant. It's said to be akin to the old (and now banned) Midnight Ecstasy. Except 1 capsule of Trip2Night is as strong as 3 of the Midnight Ecstasy. The effects are an increase in sensitivity, stimulation and an intense euphoric feeling... On three or four pills Trip2Night becomes like LSD! Many people experience hallucinations, laughter, irrational thinking, and over-the-top euphoria. It's like a mix between Ecstasy and LSD. It could get a little scary. Trip2Night is inspiring some tremendous trip reports and multiple repeat buys. You will be amazed at how much it feels like the real Ecstasy! Warning: Contains Ephredra [sic].”

- **Dream Awake tablets**

“A dose of this is the amazing combination of 2 Trip2Night tablets and 4 Benzo Berries tablets. Enter a trance-like euphoric state. You're awake, but are walking in a dream full of surreal giddiness. You already know how incredibly potent Trip2Night and Benzo Berries are. Put them together and follow Alice through the looking glass. Just be sure to have a tripsitter with you! Warning: Contains Ephredra [sic].”

- **Organic Ecstasy tablets**

“This is the strongest pure ecstasy alternative the Ecstasy Company makes. If you want MDMA effects without subjecting your brain to chemicals, this is a safe bet. You will feel the energizing and euphoric effects with the first dose. Then have a bottle full of pills left over to dance to again and again. NEW! Now they've added Soma Fly Agaric Mushrooms to the ingredients!”

- **Bliss Extra capsules**

“The key ingredient in Bliss Extra is the Aserone contained in its Calamus extract. Aserone is converted into TMA-2, which is the basic building block from which most modern amphetamines were originally derived. The Ecstasy like hallucinogenic properties of the Aserone, together with the stimulating properties of the Sida extract, makes [sic] Bliss Extra the first true Ecstasy alternative.”

- **Road Runner Super capsules**

“Road Runner Super is the most effective and carefully designed legal stimulant available. The carefully balanced herbal extract and amino acid formula gives an overall stimulation of the body, mind and spirit, that won't let you down. The main active ingredient is our Sida extract, which gives an amphetamine like stimulation of the CNS with excitation of the peripheral nervous system giving fine rushes and a tingling of the skin and hair. Its unique combination of ingredients work [sic] synergistically to make this a product without rival.”

### STIMULANTS

- **Ex-1 capsules**

“Ex-1 is 100% natural and pure Sida cordifolia extract. Sida is the ultimate natural stimulant. It works by activating a whole group of stimulant receptors, giving the ultimate comprehensive stimulation. 6-8 hours of remarkable physical and emotional energy, with sharp mental clarity, rushes, and ...”

### HALLUCINOGENS

- **Space Cadets capsules**

“Space Cadets are an uplifting natural and legal psychedelic, that will take you to another dimension. Space Cadets contain a mind expanding mix of a natural source of D-lysergic acid amide, together with herbal stimulants, to take you to a new realm of consciousness. Giggly, surreal, and paranoia free.”

- **Druids Fantasy capsules**

“Take a trip to a mystical and psychedelic land, with this, the ultimate legal and natural psychedelic. Druids Fantasy contains a natural source of D-lysergic acid amide, together with intoxicating herbal extracts, for a truly visionary experience.”

- **Ayahuasca tablets**

“This is an extremely potent hallucinogen once the tablets are activated in the same way the vine would be. It contains the most potent naturally occurring mono amine oxidase inhibitors known to man. The active ingredient is pure high grade amazonian banisteriopsis caapi vine extracted using Co2 cold extract in tableted form. Natives from the Amazon regions of South America have used this vine to induce a strong long-lasting hallucinogenic state for generations.”

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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. 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.

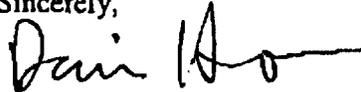
We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and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

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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