



MAR 31 2003

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Mark Hurlbut
PMB 172 - 6611 W. Peoria Avenue
Glendale, Arizona 85302

Ref. No: 03-HFD-312-03

Dear Mr. Hurlbut:

This letter is written in reference to your firm's marketing of various products that are promoted on your Internet web sites, www.getstonedlegally.com and www.stonedlegally.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:

- **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."

- **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."

- **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 Bliss Extra the first true Ecstasy alternative."

- **Salvia 5X vials**

"Salvia Divinorum 5X extracts . . . Finest legal highs like salvia divinorum."

- **Third Eye Blind herbs**

"A secret mixture of several Visionary species, all from the Lamiaceae/Labaiatae Family. . . . Extremely nice when sprinkled with a touch of Salvia 5X in a pipe. Nice, relaxing and mellow."

- **Uraeus Liquid Speed**

"Gives you a natural high without any harmful side effects. Tons of energy to keep you clubbing all night long."

- **Uraeus Liquid Buzz**

"Produces a floaty like buzz with a huge energy boost to keep you in the party mood with no side effects. The energy is not like the usual stimulant highs that make you shaky and nervous. Very clean stimulant and outstanding product."

- **Uraeus Liquid Rave**

"Produces a strong stimulant effect and mood enhancing properties. Intensifies colors, sounds, and makes raving much more fun."

- **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 euphoria. 100% stimulation!"

- **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 synergistically to make this a product without rival.”

- **T 2NIGHT aka Midnight, Red Dawn or Trip 2 Night capsules**

“ ‘Take the red pill, and I’ll show you how deep the rabbit hole goes...’ Do yourself a favor and give this a chance. It’s one of our newest products and is already inspiring multiple repeat buys. . . . Warning: Contains Ephredra [sic].”

- **Dream Awake capsules/tablets**

“This is the amazing combination of two, T 2 Night capsules and four Blue Berries tablets. Customers mixed these two dietary supplements on their own and told us of the amazing benefits. We offer them both for sale in one package! Warning: T 2 Night contains Ephredra [sic].”

- **SNUFFADELIC aka Shaman’s Snuff**

“After months of searching, WE FOUND IT! This is not Kanna. This is not TOE’s White Powder or Blow. This is the genuine Snuffadelic/Shaman’s Snuff product... It is stronger than Trip2Night. This is a potent c*ke alternative. An extreme energizer and aphrodisiac. One gram is easily 8 doses. Don’t snort it. Mix three taps of the vial with a carbonated beverage and drink. You will start glowing in 8-10 minutes.”

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.

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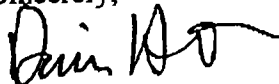
This letter is not intended to be an all-inclusive review of your Internet web site or all of your firm's labeling and products, and it is not intended to be an all-inclusive list of violations concerning your firm and its products. You are responsible for ensuring that all products marketed by your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