

WARNING LETTER

President/Owner
Herbtech
204 Grandview
Church Hill, Tennessee 37642

Ref: 02-HFD-312-15

Dear Sir or Madam:

This letter is written in reference to your firm's marketing of various products, some of which purport to contain ephedra or ma huang, that are promoted on your Internet web site, www.rxherbstore.com, as alternatives to illicit street drugs.

Your Internet web site, from which these products may be ordered, promotes these products with brand names or claims, or both, indicating that they are useful as street drug alternatives, as follows:

ENERGIZING HERBS:

- **Trip2Night:**

"If you remember and liked *Midnight Ecstasy*, You are going to love Trip2Night. . . . It is the best MDMA (Ecstasy) alternative in existence and many people report that it may work well as an antidepressant . . . Dosage: 1 pill – anti-depressant. 2 pills – increased euphoric feeling, body buzz. 4 pills – Intense euphoric feeling with hallucinations. Warnings: . . . experience hallucinations, irrational thinking . . . If you aren't familiar with LSD, it may frighten you!! Feels like a mix of LSD and Ecstasy."

"Ingredients: Ma Huang, Guarana, 5-htp, Bioperine, Indian Bromine, Cinnamon, Cola Nut, Niacin, Fo Ti"

- **Cloud 9:**

"All natural, organic, herbal stimulant, containing ephedra. This is the original cloud9 that had been banned in certain states, but now is legal."

"Illegal counterpart: Crystal Meth, Cocaine, MDMA"

- **Hype-N-Chill:**

"... It's the best buzz you'll ever get! Hype-N-Chill is packaged to included (sic) Trip2Night & Benzo-Berries. Taking one Trip2Night and two Benzos-Berries (sic) and it's the best buzz you'll every (sic) experienced (sic) – . . . The best stimulant of Trip2night and the great sedative of the Benzo-Berries. You'll be Huped (sic) but chilled. . . ."

- **Legal Speed:**

"Stronger than Yellowjackets, this is our number one seller for recovering cocaine and crystal meth addicts . . . It will increase mental and physical activity . . . and keep your body buzzing all night long."

“Illegal counterpart: Cocaine, Crystal Meth, Yellowjackets”

- **EX-1:**

“This is the ultimate natural stimulant... rushes and sheer euphoria.”

“Illegal counterpart: Crystal meth, cocaine, rush”

RELAXATION HERBS:

- **Benzo-Berries:**

“The **best herb sedative period!** The buzz is hard to describe . . . but It (sic) feels like a mix of Loritab, Soma, and Xanax. Excellent for pain, anxiety, insomnia and just for feeling extremely relaxed and stress free. . . . Taking 4 pills feels as strong as a shot of morphine! . . . This product knocks all the other herbal sedatives clear out of the water. If you enjoy painkillers, minor tranquilizers and/or muscle relaxers. Illegal Counterpart: Morphine, Heroin, GHB, Benzodiazapenes, Restoril and Soma.”

- **Magic Mushrooms II:**

“To some it is real relaxing like a xanax or a muscle relaxer/painkiller, others say that feel (sic) like real shrooms which is full of energy and vitality. The effects last for 4-8 hours. . .”

“Illegal counterpart: Shrooms, LSD, Codeine, Marijuana”

LIQUID HERBS:

- **Liquid Buzz:**

“Produces a floaty (sic) like buzz with a huge energy boost to help keep you in the party mood with no side effects. The energy is not like the usual stimulant high that make you shaky and nervous”

- **Liquid Speed:**

“Gives you a natural high . . . Tons of energy to keep you clubbing all night long.”

MIND EXPANDING HERBS:

- **Salvia 5X:**

“Salvia is probably the most potent legal or illegal herb in existence. Lucid dreaming while you are awake, out of the body experiences, auditory hallucinations as well as visual hallucinations have all been reported. **WARNING:** Anyone who is not familiar with hallucinogen’s (sic) and psychedelic experiences may have overwhelming and even frightful experiences with Salvia 5X.”

“Illegal counterpart: PCP, LSD”

- **Snuffadelic:**

“... see what our customers say about Snuffadelic.”

“... it felt like an acid trip ... This stuff and your Trip2Night are the best highs there are ... - Allen (San Diego, Ca)”

“I had all the tingles of ecstasy and the visuals of lsd and the self-esteem like cocaine. ... - William (Louisiana)”

“... It is similar to acid but almost has an ecstasy feeling as well ... It really feels good if you mix it with Trip2Night. Talk about a trip. ... - Mark L. (Newark, NJ)”

“... I felt like I had taken a few hits of blotter acid. ... My vision and sound was (sic) intense. I had minor hallucinations. It was the bomb !!! ... - A Customer for Life”

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 to 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 the document, "Guidance for Industry Street Drug Alternatives". This document is available at the Internet web site, <http://www.fda.gov/cder/guidance/index.htm>.

Based on the claims cited above, the products 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 nor all labeling and products your firm markets. The violation described above 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.

Address your reply to the Food and Drug Administration, Division of Labeling and Nonprescription Drug Compliance (HFD-310), 7520 Standish Place, Rockville, MD 20855, Attention: Joel Aronson.

Sincerely,

David J. Horowitz
Acting Director
Office of Compliance
Center for Drug Evaluation and Research