



MAR 31 2003

WARNING LETTER

Food and Drug Administration
Rockville MD 20857

VIA FEDERAL EXPRESS

Mr. Shaun Roberts
12051 Tuscany Bay Dr.
#303
Tampa, Florida 33626

Ref. No: 03-HFD-312-09

Dear Mr. Roberts:

This letter is written in reference to your firm's marketing of various products that are promoted on your Internet web site, www.recreationalherbs.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:

- **TRIP2NIGHT capsules**

"... We feel is the best mood enhancing, energizing product available on the market. Trip2night is said to be virtually [sic] the same as the (now banned) Midnight Ecstasy. Except 1 capsule of Trip2Night is as strong as 3 of the Midnight Ecstacys. The effects are an increase in sensitivity, stimulation, and an intense euphoric feeling... Beware... taking 3 or 4 Trip2night at a time may produce hallucinations, irrational thinking. Ingredients: MaHuang, Gurana, 5-HTP, Bioperine, Indian Bromine, Cinnamon, Cola Nut, Niacin, Fo ti Gotu-kola, Green Tea Extract, Rou Gui."

- **BENZOBERRIES pills**

"Excellent for pain, anxiety, insomnia and just for feeling extremely relaxed and stress free... This product is good at lowering anxiety and helping you get a good nights sleep. To produces [sic] different euphoric feelings, mix benzoberries with Trip2night to have custom experiences. Mixing the BenzoBerries and Trip2night in equal quantities brings a effect [sic] neither will produce alone. Ingredients: 5-HTP EXTRACT 10X, Phenepropaloxamine, Valerian Root Extract 10X, Wild Berry Extract 10X, Kava Kava Extract 10X, Bioperime."

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,

A handwritten signature in black ink, appearing to read "David J. Horowitz". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

David J. Horowitz, Esq.

Director

Office of Compliance

Center for Drug Evaluation and Research