DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 31 2003

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. John Hoover
213 Erie Street
Edinboro, Pennsylvania 16412

Ref. No: 03-HFD-312-12

Dear Mr. Hoover:

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

- **Herbal Ecstacy capsules**

  "The most effective alternative on the market right now[.] These are the ultimate in satisfaction, our best yet! Many, [sic] of our customers enjoy the enhanced effects received from this herbal product."

- **TRIP 2 NIGHT capsules**

  "Herbal Ecstasy ... These are no joke ... *Warning* Trip2Night contain [sic] Ephedra ... Ingredients: MaHuang [sic], Gurana, 5-HTP, Bioperine, Indian Bromine, Cinnamon, Cola Nut, Niacin and Fo Ti[.] Personally, we don't know how these are legal, yes they are that strong."

- **Ecstacy Explore capsules**

  "These have been time tested in Amsterdam, the drug capital of the world. ... alternative ecstasy"

- **EX-1 capsules**

  "Herbal Ecstasy ... 100% natural and pure: Sida Cordifolia extract. Sida is the ultimate natural stimulant. The main active ingredient is Sida cordifolia extract, which contains L-Ephedrine. Ephedrine is a natural amphetamine that gives

stimulation of the central nervous system (CNS), similar to speed (but to a lesser extent,) along with the excitation of the peripheral nervous system, that is far greater than that associated with Speed. This peripheral activity is what gives the rushes and the tingling of the skin and hair. Exercise upon EX-1 will produces [sic] masses of rushes. The nature of Ephedrine assures that the overall effects are markedly different from those associated with Speed and other abused Amphetamines."

- **Ecstacy Rush capsules**

  "Ecstacy Rush is powerful giving full body stimulation. Need to be in a rush? These will do it"

- **EK-STA-SIS capsules**

  "ek-sta-sis –the original form of the word ecstacy. In Greek it originally referred to the separation of the soul from the body. This is a truly unique ecstacy experience. Sida Cordifollia [sic] ..."

- **Road Runner Super capsules**

  "The main active ingredient is our Sida extract, which gives an amphetamine like stimulation, giving massive rushes and a tingling of the skin and hair. Its unique combination of ingredients works synergistically to make this a product without rival."

- **Ecstacy Tripadelic capsules**

  "Ingredient are [sic] Fly Agarc "soma" mushrooms, Grifola Frondosa "dancing mushrooms" chuchuhuasi & mugwort"

- **Salvia Divinorum 5X extract**

  "NOW ILLEGAL IN AUSTRALIA Salvia is scheduled by the DEA to be illegal in the USA Soon [sic], Better Stock Up Now! Salvia Divinorum is an extraordinary herb used in shamanism, divination, healing, meditation, and the exploration of consciousness ... in search of a psychedelic plant known to be used by Mexican Indians, for spiritual journeys. What they found was the Most Potent Naturally Occurring Psychedelic Plant. Salvia Divinorum. WARNING: Anyone who is not familiar with hallucinogen's [sic] and psychedelic experiences may have overwhelming experiences with Salvia 5X.

> A trip-sitter is mandatory for this product. If you don't trust the dark recesses of your own mind then pass on this ... You need a pipe to smoke it, bongs are not good for this kind of concentrated extract ... The experience is 20 minutes of intense auditory and visual hallucinations, then a pleasant long lasting stoned feeling."

"Smokables"

- **Trance Joint**
- **Space Joint**
- **Super Joint**
- **Fantasy Joint**
- **Relax Joint**

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

cc:
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