



Food and Drug Administration
Denver District Office
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Denver, Colorado 80225-0087
Telephone: 303-236-3000
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January 3, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jordan X. Rand
Chief Executive Officer
Xavier Enterprises/Xavier Exotic Herbs
743 Gold Hill Place
Woodland Park, CO 80866

and

Mr. George P. Dreher
President
Adult Site Services, Inc.
P.O. Box 75643
Tampa, FL 33675-0643

Ref. # - DEN-02-09

Dear Messrs. Rand and Dreher:

This letter is in reference to the promotion, marketing, and distribution of "Seventh Heaven" Kathmandu Temple Kiff by your firms, Xavier Enterprises/Xavier Exotic Herbs and Adult Site Services, Inc.

The label for "Seventh Heaven" Kathmandu Temple Kiff bears the following objectionable claims:

- "A "Sensative" Himilayan Botanical Stoke-Smoking Substance for Blissful Regressions of Vexatious Depressions..."
- "Kathmandu Temple Kiff is indeed a preferential herbaceous "Sensitive" pipe smoking substance."
- "It is both a euphoriant and a calmativ/relaxant that offers scintillating physical and cerebral ambiance/enhancement."

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- “In order to enjoy Kathmandu Temple Kiff to maximum advantage; draw from the pipe 4-6 times and retain each “stoke” as long as possible.”

“Seventh Heaven” Kathmadu Temple Kiff is marketed and promoted through the Internet web site, www.legallystoned.com, with claims that represent and suggest the product is useful as an alternative to illicit street drugs. Further, in the context of this web site, the web site name is itself a claim for the product’s use as an alternative to illicit street drugs.

This website contains objectionable claims such as:

- “LEGALLY STONED A “Sensitive” Himalayan Stoke-Smoke”
- “Kathmandu Temple Kiff is a herbaceous, “**Sensitive**” pipe smoking substance. It is both a **euphoric** and a **calmative relaxant** that offers **tremendous physical and mental enhancement.**”
- “The indulgence of this particular kiff accomplishes a most interesting duality of physical and mental relaxation and enhancement.”
- "As well, given the euphoric properties of Kathmandu it is also appropriate to say that this herbaceous stoke-smoke is a robust anti-depression, anti-anxiety, mood-enhancing device that ushers in; "Blissful Regressions of Vexatious Depressions"."
- "And certainly while Kathmandu Temple Kiff does maintain a kindredness with Cannabis/Marijuana it most definitely possesses its own unique character, rendering a more dignified contingency than Cannabis/Marijuana and a rather collected sort of poise as opposed to the scatteredness and paranoia that Cannabis/Marijuana often imparts ..."
- "Kathmandu Temple Kiff is also noted for it's (sic) ambiance regarding the enhancement of the (Tantra Sacramental) ... lucid dreaming activity."
- “Just a snippet of the “Kathmandu” travels such a long, “Sensitive” way... **Four or five stokes of your pipe lasts for up to 2 to 3 hours or so!!!.**” (A free herb pipe and usage instructions are included with each Kathmandu Temple Kiff Pakage.)”
- “3 to 5 tokes last around 3 hours.”
- "You cannot find this product in "head shops" ..yet."
- “I received my package of Kathmandu Temple Kiff... And I was completely blown away by the results. ... I like to smoke weed, and I thought that nothing that is 100 percent legal could actually get me stoned, but I was wrong! ... It’s definitely very effective in producing a very euphoric high.”

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- “Now I just can’t believe how easy it is to be legally stoned! ... It’ (sic) gets me high ... no one can tell I’m high.”
- “To my surprise, 3 or 4 tokes and I’m ripped.”

Based on these claims in the labeling, “Seventh Heaven” Kathmandu Temple Kiff is a “drug” within the meaning of section 201(g) of the Food, Drug and Cosmetic Act (the Act). Moreover, it is also a “new drug” [section 201(p) of the Act] because there is no evidence that this product is generally recognized as safe and effective for its intended use. Since this product is a “new drug”, it may not be legally marketed in the United States without an approved new drug application [section 505(a) of the Act].

We note that your firm may be marketing other products with similar or related claims. Such claims may also cause those products to be drugs, new drugs and misbranded drugs. This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

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 the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. The response should also include the intentions of Adult Site Services, Inc. to promoting and marketing similar or related “Seventh Heaven” Kathmandu Temple Kiff on their web site by other affiliates. 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 implemented.

Your reply should be sent to the attention of H. Tom Warwick, Compliance Officer, at the above letterhead address.

Sincerely,



B. Belinda Collins
Acting Director, Denver District

cc: U.S. Food & Drug Administration
Orlando, FL

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