DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

HFD-205

WARNING LETTER AUG 29 1997

Mr. Sean S. Shayan
Global World Media Corp.
1501 South Main Street, Unit #203
Venice, California 90292

Ref: No. 97-HFD-310-02

Dear Mr. Shayan:

This letter notifies you that your drug product,"herbal ecstacy™," is in violation of the Federal Food, Drug, and Cosmetic Act (the FFDCA). The product is labeled as containing Tibetan Ma Huang, wild Brazilian guarana, Chinese black ginseng, wild ginko biloba, African raw kola nut, gotu-kola, pho-ti-tieng, green tea extract, and rou gui (a rare form of Chinese nutmeg).

"herbal ecstacy™" is identified in promotional material as "Soar into ecstacy . . . The world's most advanced designer nutritional supplement herbal ecstacy™ is more than just another smart drug. it is a carefully formulated and thoroughly tested organic alternative . . . A fantastically light headed, tingly happy, happy buzz with no side effects . . . The effects of herbal ecstasy™ beyond smart drug capacity include: euphoric stimulation . . . high increased energy levels . . . enhanced sensory processing . . . mood elevation." These street drug alternative claims, and the use of the name "herbal ecstacy™," do not fall within the scope of claims permitted for dietary supplements.

As labeled, "herbal ecstacy™" is a drug as described in §201(g) of the FFDCA and a "new drug" as described in §201(p) of the FFDCA which may not be legally marketed in the United States without an approved New Drug Application. In addition, it is misbranded as described in §502(f)(1) of the FFDCA because its labeling fails to bear adequate directions for the uses for which it is being promoted.

The claims and name indicate that "herbal ecstacy™" is offered for abuse and misuse purposes. As such, there is no legitimate drug use for this product and its continued marketing is illegal.

We request you take prompt action to correct these violations. Failure to promptly correct them may result in enforcement action being initiated by the Food and Drug Administration without further notice. The FFDCA provides for seizure of illegal products (§304) and for injunction (§302) against the manufacture and/or distribution of illegal products.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations.

Your reply should be sent to the Division of Labeling and Nonprescription Drug Compliance, HFD-310, Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

Bradford W. Williams
Director
Division of Labeling and Nonprescription
Drug Compliance
Office of Compliance
Center for Drug Evaluation and Research