DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 14 2001

WARNING LETTER

Jose I. Iparraguirre, MD
President
JIIM, L.L.C.
7700 N. Kendall Drive, Suite 604
Miami, Florida 33156

Ref: 01-HFD-312-02

Dear Dr. Iparragirre:

This letter concerns "Doctor's Lotion" marketed by your firm. Based on this product's labeling, it is intended for topical over-the-counter (OTC) use by women as an aphrodisiac to enhance arousal and improve the sexual experience. Thus, "Doctor's Lotion" is a "drug" under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The intended uses described above are conveyed through labeling, which includes statements such as, "Doctor's Lotion is the first stimulus enhancing lotion created for women to improve the sexual experience by enhancing arousal. The active ingredients in Doctor's Lotion have shown [sic] to increase the blood flow to the clitoris and surrounding area by gently and safely dilating blood vessels. The increase in blood flow improves the sensation of the nerve endings in the clitoris to enhance arousal and promote orgasm." In addition, you use similar statements in your current Internet promotion for "Doctor's Lotion" along with statements like "...aid[ ] women's sexual satisfaction...," "...aid women experiencing the significant problem of sexual dissatisfaction...," "...improving the quality of intimacy, and enhance their overall sexual experience...," and "...heightens the sensation of a woman's sexual organs...".

The immediate container label for "Doctor's Lotion" identifies "Aminophylline," "Ergoloid Mesylate," "Arginine," and "Isosorbide Dinitrite" as "active ingredients". A flyer distributed with the product identifies "Deionized Water," "Glycerin," "Vitamin E Gel," "Aminophylline," and "L-Arginine" as "active ingredients," while current Internet promotion identifies "Glycerin," "Vitamin E," "Theophylline," and "Arginine" as "active ingredients".

Regardless of the formulation, under Title 21 of the Code of Federal Regulations, Part 310.528 (21 CFR 310.528) (copy enclosed) any OTC drug product that is labeled, represented, or promoted for use as an aphrodisiac, like "Doctor's Lotion," is regarded as a "new drug" within the meaning of Section 201(p) of the Act. These regulations require that such drugs have an approved application under Section 505(b) of the Act before they

can be marketed. Thus, "Doctor's Lotion" violates Section 505(a) of the Act. Further, since the adequacy of the labeled directions for these "aphrodisiac" uses has not been established, this product is misbranded under section 502(f)(1) of the Act.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may consider this information when considering the award of contracts.

We request that you take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. It should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Address your reply to the Food and Drug Administration, Division of Labeling and Nonprescription Drug Compliance, OTC Compliance Team (HFD-312), 7520 Standish Place, Room 168, Rockville, MD 20855, Attention: Vesna V. Stanoyevitch, Compliance Officer. If you have any questions about this letter, you may contact Ms. Stanoyevitch by telephone at 1-301-827-7362.

Sincerely,

Melvin F. Szymanski
Acting Director
Division of Labeling and
Nonprescription Drug Compliance (HFD-310)
Office of Compliance
Center for Drug Evaluation and Research

Enclosure:
21 CFR 310.528