



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
New Orleans District
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

October 20, 1999

CERTIFIED - RETURN RECEIPT REQUESTED

Mr. Thomas C. Alsup
President
Genesis Natural Products, Inc.
2819 Dogwood Place
Nashville, TN 37204

Quigley
10/21/99
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WARNING LETTER - 00-NSV-01

Dear Mr. Alsup:

This letter is about "All Natural Ginesis Exclusive Formula Shampoo," "Progesterone 950 mg Natural Woman Essential Body Cream," and "Pregnenolone Natural Aura Arthritis Joint Relief" drug products that your firm distributes.

The "All Natural Ginesis Exclusive Formula Shampoo" contains, among other things, cotyledon berry extract, fennel extract, cocamide, hops extract, spearmint oil, yarrow extract, balm mint, and mistletoe extract. The labeling, including information on your Internet web site, bears claims that the product "...can correct oily or dry scalp, itching...dandruff, and hair loss caused by chemicals in most shampoos. While dandruff shampoos claim to treat the constant flaking, Ginesis natural shampoo treats the problems that cause the flakes...Ginesis shampoo helps control hair loss, dandruff...and controls itchy scalp...Cotyledon Berry Extract...has been used...to treat all types of hair and scalp problems, and to prevent hair loss." Based on these claims, the product is a drug (section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act)). Further, the product is subject to regulations covering OTC dandruff preparations found in Title 21 Code of Federal Regulations (21 CFR) part 358.701 and regulations covering OTC hair growth products found in 21 CFR 310.527. The product's formulation and labeling fail to comply with these final regulations.

The "Progesterone 950 mg Natural Woman Essential Body Cream" contains, among other things, natural glycerin, stearyl konium chloride, vitamin E, avocado oil, cotyledon plant, natural progesterone (derived from the Mexican wild yam root), dong quai, saw palmetto, cramp bark, sarsaparilla, carrot oil, and lemon grass oil. The labeling, including material on your Internet web site, claims

that the "...Transdermal natural progesterone cream offers an effective, nonprescription alternative therapy with none of the serious risks or unwanted side effects of estrogen replacement... Prevent endometrial cancer...Protects against breast cancer...Protects against fibrocysts...reverse osteoporosis..." Based on these claims, the product is a drug. We are not aware of any evidence that the combination of ingredients is generally recognized as safe and effective for the intended uses of the product. Further, because the product contains the hormone progesterone, it is subject to the final regulation on OTC hormone drug preparations found in 21 CFR 310.530. The product does not comply with this final regulation.

The "Pregnenolone Natural Aura Arthritis Joint Relief" contains, among other things, glucosamine, natural glycerin, stearyl konium chloride, cotyledon plant, and pregnenolone. The labeling, including information on your Internet web site, offers the product for use in "Arthritis - Joint Pain - Shingles - Sprains...Pregnenolone may help play a role in memory, mood, energy, PMS, menopause, hormone replacement, stress reduction, immunity, arthritis..." Based on these claims, the product is a drug (section 201(g) of the Act). We are not aware of evidence that the combination of ingredients in the product is generally recognized as safe and effective for the claims in the labeling. Because the product contains the hormone pregnenolone, it is also subject to the final regulation covering OTC hormone drug preparations found in 21 CFR 310.530. The product does not comply with this final regulation.

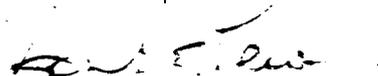
Based on the formulations and claims, the products listed above are "new drugs" (section 201(p) of the Act). A "new drug" may not be marketed in the United States without an approved new drug application (NDA) (Section 505(a) of the Act). In addition, these products are also misbranded (section 502(f)(1) of the Act), because they do not bear adequate directions for the indications noted above.

The violations cited in this letter are not intended to be an all-inclusive statement of the violations that may exist for products marketed by your firm. It is your responsibility to assure that all your drug products are in compliance with federal laws and regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs and devices so that they may take this

information into account when considering the award of contracts. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of your receipt of this letter of the specific steps you will take to correct the noted violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and time frame within which corrections will be completed. Your reply should be sent to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Howard E. Lewis
Director, Nashville Branch
New Orleans District Office

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Enclosures:

- 21 CFR 310.527
- 21 CFR 310.530
- 21 CFR 330.1 Subpart A
- 21 CFR 358 Subpart H