



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

May 12, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUIRED

Ronald K. Williams
President
Whole Living, Inc.
D.B.A. Brain Garden
Suite 201
American Fork, UT 84003

Ref. #: DEN-00-26

Dear Mr. Williams:

This letter is in reference to the marketing and distribution of the product, Pro L'ève. Promotional material (labeling) makes therapeutic claims which cause the product to be a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Claims for the product include "Natural Progesterone Cream," "...suffers from the symptoms of severe progesterone deficiency? ...depression. ... headaches...", "... epidemic of hormonal imbalance in women and men ... Progesterone will help end the discomforts of menstruation, premenopause, menopause, and osteoporosis without the worry of dangerous side effects from synthetic hormones...", "...studies have proven natural progesterone's role in the prevention and treatment of breast, uterine, and other female related cancers...protection against breast cancer, normalizing thyroid function and improved skin conditions such as acne, seborrhea, rosacea, psoriasis and keratoses...", and "...important in the prevention and/or treatment of prostatism and prostate cancer. "

Further, a final rule addressing topical hormone cream was published in the Federal Register of September 9, 1993, and codified at Title 21 Code of Federal Regulations Part 310.530. This final rule declares all over-the-counter drug products containing hormone ingredients to be new drugs. A copy of the rule is enclosed.

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The product is a "new drug" because there is no evidence that it is generally recognized as safe and effective for this intended use [Section 201(p) of the Act]. Therefore, it may not be legally marketed in this country without an approved New Drug Application [Section 505(a) of the Act].

The drug is also misbranded because its labeling fails to bear adequate directions for use for the conditions for which it is offered [Section 502(f)(1) of the Act]. The labeling is false and misleading as it suggests that the product is safe and effective for its intended uses when, in fact, this has not been established [Section 502(a) of the Act].

Your website, www.thebraingarden.com, includes similar claims that demonstrate your intended drug use for the product, Pro L'ève.

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 these 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, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not occur. 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 directed to Jeannette A Schmieg, Acting Compliance Officer, at the above address.

Sincerely,



Karen S. Kreuzer
Acting District Director

Enclosure:
21 CFR 310.530

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