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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

609

297 Plus Park Boulevard
Nashville, TN 37217

July 3, 1997

*Quoted 7/3/97
JEA*

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Frank Vandersloot, Chief Executive Officer
Melaleuca, Inc.
3910 S. Yellowstone Highway
Idaho Falls, ID 83402

Warning Letter No. 97-NSV-08

Dear Mr. Vandersloot:

This letter is in reference to an inspection of your firm in Knoxville, Tennessee, on February 6-11, 1997, which revealed the marketing and distribution of "ProVex", "ProVex-Plus", and "Replenex" which are being promoted to treat disease conditions.

The promotional material (labeling) makes claims for "ProVex" that include:

- that it protects as a "disease fighting antioxidant" against "chronic degenerative disease including heart disease, cancer and arthritis."
- "platelet inhibitory activity...increased platelet activity can contribute to the rate of development of atherosclerosis and is associated with initiating coronary artery thrombosis or clot formation."
- "Recent studies now show that there is an inverse relationship between flavonoid intake and the incidence of heart disease" implying that "ProVex" lowers the incidence of heart disease.
- that it reduces free radicals that "can lead to degenerative diseases such as atherosclerosis, cancer, arthritis and can negatively impact the immune system and the aging process" implying "ProVex" can prevent or treat these diseases.

Your claims for "ProVex-Plus" include:

- that it protects as a "disease fighting antioxidant" against "chronic degenerative disease including heart disease, cancer and arthritis."
- "platelet inhibitory activity...increased platelet activity can contribute to the rate of

development of atherosclerosis and is associated with initiating coronary artery thrombosis or clot formation" implying "ProVex-Plus" can prevent or treat atherosclerosis or coronary artery thrombosis.

- "If LDL cholesterol is oxidized, it becomes more atherogenic to artery walls. Studies have shown that the powerful antioxidant properties of proanthocyanidins and bioflavonoids help to reduce the incidence of LDL cholesterol oxidation."

The claims made for your product "Replenex" include:

- "an alternative in the treatment of degenerative joint disease or common osteoarthritis."
- "...addresses the underlying cause - not just the symptoms - of osteoarthritic joint pain"
- "halting and possibly reversing the process of articular cartilage degeneration."

Your promotional brochure (labeling) makes therapeutic claims for these products which cause them to be drugs as defined under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). These products are also "new drugs" under Section 201(p) of the Act and, therefore, they may not be legally marketed in the United States without approved New Drug Applications as stated in Section 505 of the Act.

These drugs are also misbranded because the labeling fails to bear adequate directions for use as stated in Section 502(f)(1) and because the labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when this has not been established as referenced under Section 502(a).

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 Food, Drug and Cosmetic 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. Such actions include, but are not limited to seizure and injunction.

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 these 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. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be implemented.

Your response should be sent to Mr. Joseph E. Hayes, Compliance Officer; Food and Drug Administration; 297 Plus Park Blvd.; Nashville, TN 37217.