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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3896

Telephone: 504-589-6341
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April 13, 1999

WARNING LETTER NO. 99-NOL-20

OVERNIGHT DELIVERY
FEDERAL EXPRESS

Mr. Donald H. Payne
Co-Owner/Manager
Piney Woods Emu Farm
155 Will Best Road
Richton, Mississippi 39476

Dear Mr. Payne:

This letter is in reference to your firm's marketing and distribution of the product, "Piney Woods Pure Emu Oil." 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).

Examples of the claims include the following:

From the bottle label:

- ◆ "For centuries virtually the only element used in Australia for a medicine, antibiotic, pain reliever, arthritis, ..."

From the promotional flyer:

- ◆ "Pure Emu Oil eliminates skin cancer in days! It works! No gimmicks! Pure Emu Oil has antiinflammatory [sic] quality when applied to inflamed or burned skin, leaving virtually no scars."
- ◆ "Known users of Pure Emu Oil have reported and know it is extremely beneficial in the treatment of rheumatism, arthritis, all bruises, cuts, ..., infections, joints stiffness, prostate problems, ulcers, sunburn, fire ant and wasp and mosquito and bee stings, poison ivy, hemorrhoids, ..., cold sores, canker sores, ..., headache, tooth ache, earache, prevention and removal of scars and pregnancy stretch marks, strain muscles, and ligaments, ..., dandruff,

retaining hair ..., baby rash, athlete's foot, warts, and more recently, cancer, heart trouble, hardening of the arteries, diabetes, and more."

- ◆ "Varicose veins? Tremendous relief."
- ◆ "Does Chemotherapy cure cancer or did Piney Woods Pure Emu Oil save this man's life?"
- ◆ "Another Doctor's report of the proven benefits of Pure Emu Oil: An 80 year old lady was referred to me by a surgeon who said it looked like they were going to have to amputate her foot. But I used Pure Emu Oil instead of amputating her foot, completely eliminating the gangrene and completely healed the open sore. I am going to continue to use Pure Emu Oil in my practice of medicine. I wouldn't quit."
- ◆ "Alzheimer's Disease!!! My husband has Alzheimer. On September 2, 1998 he began eating 1 teaspoon full of Piney Woods Pure Emu Oil each day. Prior to this he was unable to do anything except sit in his chair & hammock, lay on his air mattress and talk about how tired he was. Now (in just 22 days) he mowed the grass, cleaned out the garage, weeded the flower beds, and we take our morning walk again. It hasn't helped his memory much yet, but he is more like himself again!!!"
- ◆ "Emu Oil lowers cholesterol." A testimonial claims that, "...my cholesterol level was 312..."
Then continues to describe being prescribed medication to treat the cholesterol problem, ignoring the physicians advice, eating high cholesterol foods and taking daily Emu Oil. "...my cholesterol had once again come down. This time it was 247."

Current Good Manufacturing Practices deviations included no process or cleaning validation, no manufacturing batch records, no finish product testing, no written procedures, and no complaint handling system.

Piney Woods Emu Oil is a "new drug" because there is no evidence that it is generally recognized as safe and effective for its 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 the 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].

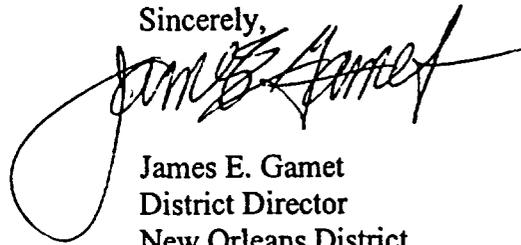
This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

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 distribution of illegal products.

Please notify this office in writing, within 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 the 15 working days, state the reason for this delay and the time within which the corrections will be implemented.

Your response should be directed to Ms. Carolyn S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, do not hesitate to contact Ms. Olsen.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", with a large, sweeping flourish extending from the bottom left of the signature.

James E. Gamet
District Director
New Orleans District

Enclosure: FDA 483