



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

July 30, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Mary B. Young, Owner
Aromatic Research & Technology, LLC
Dba Young Living Essential Oils
250 S. Main Street
Payson, Utah 84651

PURGED

Dear Ms. Young:

This letter is written in reference to the marketing of Esspro 7 by your firm. Our analysis shows EssPro 7 to contain from 1.1 mg/g to 1.1 mg/g. The “intended uses” for EssPro 7 suggest and represent that it is offered for drug use. Specifically, it is intended to affect the structure or any function of the body, and to treat disease and, therefore, is a drug as described in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Further, we are unaware of any substantial scientific evidence which demonstrates that this drug is generally recognized as safe and effective (see 21 CFR 310.530). Accordingly, marketing of this drug is a violation of the Act as follows:

The drug is misbranded within the meaning of Section 502(a) in that its labeling is false and misleading because it represents and suggests that there is substantial scientific evidence to establish that the drug is safe and effective for its intended uses when in fact such evidence does not exist.

Additionally, the drug Esspro 7 is further misbranded pursuant to Section 502(f)(1) in that its labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since the conditions for which it is offered is not amenable to self diagnosis and treatment by the laity; therefore adequate directions for use cannot be written.

This letter does not represent a comprehensive review of all the products your firm distributes. It is your responsibility to assure that all requirements of the Federal FD&C Act and regulations promulgated thereunder are being met.

We request that you reply within fifteen (15) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug or otherwise bring it into compliance.

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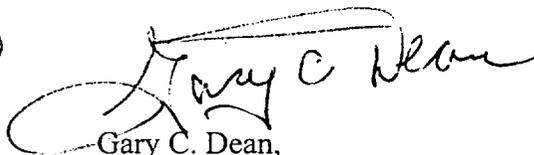
Your response should include: (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which correction will be completed; (3) any reason why the corrective action has not been completed within the response time; and (4) any documentation necessary to show that correction has been achieved.

Failure to promptly correct these deviations may result in enforcement action being initiated without further notice. The Food, Drug and Cosmetic Act provides for seizure of illegal products (Section 304) and for injunction (Section 302) against the manufacturer and/or distributor of illegal products. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the award of contracts.

Your reply should be directed to the attention of Ms. Shelly L. Maifarth, Compliance Officer, Food and Drug Administration.

Sincerely,

PURGED



Gary C. Dean,
Director, Denver District

Attachment:
21 CFR 310.530

cc: D. Gary Young, Managing Director
Young Living Essential Oils
250 S. Main Street
Payson, UT 84651