



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 27 2000

01 JAN -2 4:35:57

Mr. David Stewart
Label Regulations
Young Living Essential Oils
250 So. Main Street
Payson, Utah 84651

Dear Mr. Stewart:

This is in response to your letter of November 29, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Young Living Essential Oils is making the following claims, among others, for the following products:

Coriander

“...for its effects in lowering glucose and insulin levels...”

Dill

“...for its supportive effects on glucose levels...”

Helichrysum

...improving skin conditions...”

Myrtle

“...help with chronic coughs and respiratory tract ailments”

Pepper, Black

“...for soothing deep tissue muscle aches and pains.”

Nutmeg

“...benefit circulation and muscle aches and pains”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 436

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-810
HFS-811 (file)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Nickerson)
f/t:HFS-811:rjm:12/15/00:docname:73614.adv:disc53



Young Living ESSENTIAL OILS™

73614

November 29, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. Street S.W.
Washington, D.C. 20204

Re: Notification for Statements on Dietary Supplement Labeling

Dear Sir/Madam:

This notification is being submitted on behalf of Young Living Essential Oils, Payson, Utah, a distributor of dietary supplement products (hereafter "Young Living").

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343 (r) (6), and in accordance with the authorized provisions of 21 CFR § 101.93 (a), your Agency is hereby notified that Young Living proposes to make and/or has made statements of "nutritional support", as described in 21 U.S.C. § 343 (r) (6) (A), for its dietary supplements as follows:

<u>Product Name</u>	<u>Statement(s)</u>
Cistus (Cistus ladanifer)	Has been studied for its effects on the regeneration of cells
Coriander (Coriandrum sativum)	Has been researched at Cairo University for its effects in lowering glucose and insulin levels and supporting pancreatic function
Dill (Anethum graveolens)	Has been researched at Cairo University for its supportive effects on glucose levels and pancreatic function
Di-Tone	Aids digestion
EndoFlex	May help overall vitality. May improve and balance metabolism. Associated with weight loss.
Femalin	An herbal and oil tincture formulated to support the female reproductive system.
FemiGen	An herbal complex with amino acids that supports the female reproductive system and maintain body balance from developmental years all the way through menopause.
Frankincense (Boswellia carteri)	Supports the immune system
Galbanum (Ferula gummosa)	It is recognized for its antiseptic and body-supporting properties.
Geranium (Pelargonium graveolens)	Its strength lies in the ability to revitalize tissue.
Goldenrod (Solidago canadensis)	Supports the circulatory system, urinary tract, and liver function



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<u>Product Name</u>	<u>Statement(s)</u>
Helichrysum (Helichrysum italicum)	Has been studied in Europe for regenerating tissue and improving skin conditions, nerves, and circulation.
Juniper (Juniperus osteosperma and/or J. scopulorum)	Supports proper nerve function
JuvaFlex	A combination of essential oils that have been studied for their effect on the liver and digestion.
Ledum (Ledum groenlandicum)	Stimulates the nerves
Lemon (Citrus limon)	Has been studied for its effect on immune function
Lemongrass (Cymbopogon flexuosus)	Used for purification and digestion
Marjoram (Origanum marjorana)	Used for soothing the muscles and the respiratory system
Mountain Savory (Satureja montana)	Used historically as a general tonic for the body
Myrtle (Myrtus communis)	Has been research by Dr. Daniel Penoel for its effects on hormonal imbalances of the thyroid and ovaries. It has also beed researched for its soothing effects on the respiratory system. Myrtle may help with chronic coughs and respiratory tract ailments.
Nutmeg (Myristica fragrans)	Helps support the adrenal glands for increased energy. Historically been used to benefit circulation and muscle aches, and pains. Helps to support the nervous system and may assist in overcoming nervous fatigue.
Patchouly (Pogostemon cablin)	It is a general tonic that supports the digestive system. Beneficial for the skin and may help reduce wrinkled or chapped skin.
Pepper, Black (Piper nigrum)	Has been used for soothing deep tissue muscle aches and pains
Peppermint (Mentha piperita)	One of the oldest and most highly regarded herbs for soothing digestion. Jean Valnet, M.D., studied peppermint's effect on the liver and respiratory systems.
Petigrain (Citrus aurantium)	Antiseptic and re-establishes nerve equilibrium
Radex	An antioxidant that helps reduce the buildup of free radicals from air pollution and radiation while detoxifying, cleansing, and building the systems of the body.



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<u>Product Name</u>	<u>Statement(s)</u>
Rosemary verbenon (Rosmarinus officinalis CT verbenon)	Has been used by Dr. Penoel and Dr. Franchomme for supporting respiration and reducing stress and frustration
Sage (Salvia officinalis)	It has been recognized for its benefits of strengthening the vital centers and supporting metabolism. May nutritionally support the body during the childbearing years and menopause.
Sandalwood (Santalum album)	Supports normal nerve function and circulation
Spearmint (Mentha spicata)	Helps support the respiratory and nervous system
Spruce (Picea mariana)	Helps support the respiratory and nervous systems
Super B	A powerful antioxidant that supports normal immune function, metabolism, energy, and overall health
Super C	A powerful antioxidant and vitamin C supplement that enhances the effectiveness and absorption of vitamin C.
ThermaBurn	A powerful modern and traditional herbal formula for enhanced carbohydrate burning. Helps to curb appetite and may help combat fatigue for enhanced weight management. Helps raise metabolism. Boosts energy.
ThermaMist	Supports normal immune function and carbohydrate burning
Ultra Young	Supports healthy pituitary function and growth hormone release
Ultra Young +	Supports growth hormone production in the body
Wolfberry Bar	A protein bar rich in the essential amino acids and minerals for building muscle and supporting normal immunity.

The undersigned certifies on behalf of Young Living Essential Oils that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,

David Stewart, Label Regulations
YOUNG LIVING ESSENTIAL OILS