Inspections, Compliance, Enforcement, and Criminal Investigations

dōTERRA International, LLC 9/22/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration

September 22, 2014

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

dōTERRA International, LLC
Attn: David Stirling
389 South 1300 West
Pleasant Grove, Utah 84062

Dear Mr. Stirling:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed websites and social media accounts (*e.g.* *www.anytimeessentials.com*, Facebook, Twitter, Pinterest, YouTube) used to promote your dōTERRA Essential Oil products in August 2014. Based on our review, FDA has determined that several of your dōTERRA Essential Oil products including, but not limited to, "Melaleuca," "Oregano," "On Guard," "Clove," "Eucalyptus," "Frankincense," "Geranium," "Lavender," "Lemongrass," "Myrrh," "Peppermint," "Rosemary," "Wintergreen," "Clary Sage," and "Vetiver" are promoted for conditions that cause them to be drugs under section 201(g)(1)(B) of the Federa Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The intended use of a product may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution, 21 C.F.R. § 201.128. As described below, th marketing of your dōTERRA Essential Oil products with drug claims and without FDA approved-applications is in violation the Act.

Your products are marketed through the website http://www.anytimeessentials.com/ and through paid "consultants," http://www.anytimeessentials.com/work-home/, otherwise referred to as "wellness advocates," http://www.mydoterra.com/. Your consultants promote your above mentioned dōTERRA Essential Oil products for conditions including, but not limited to, viral infections (including ebola), bacterial infections, cancer, brain injury, autism, endometriosis, Grave's Disease, Alzheimer's Disease, tumor reduction, ADD/ADHD, and other conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners. Moreover, your consultants redirect consumers to your website, www.doterra.com, to register as a customer or member (*i.e.*, consultant), and to purchase your dōTERRA Essential Oil products.

Examples of claims observed on your various consultant websites and social media accounts that establish the intended uses of your essentia oil products include, but are not limited to the following:

On the website, www.anytimeessentials.com:

Under the heading, "Fight Your Virus with Essential Oils":

• "Melaleuca: Melaleuca (also known as tea tree oil) has been clinically shown to inhibit the replication of the influenza virus. Some of melaleuca's primary uses include . . . athlete's foot . . . canker sores, chicken pox, cold sore, colds, flu, fungal infections, Herpes simplex, MRSA, shingles, warts and viral infections."
• "Oregano: Oregano is effective in inactivating MNV (non-enveloped murine norovirus) within 1 hour of exposure. Some of the primary uses for oregano include athlete's foot, candida, canker sores, Ebola virus, intestinal parasites, MRSA, ringworm, staph infection, viral infections, warts, and whooping cough."
• "On Guard: On Guard is a blend of dōTERRA oils and it has been lab tested to decrease symptoms of the flu. Some of the primary uses of On Guard include antiviral, cold sores, colds, flu . . . infection, lupus, MRSA, pneumonia . . . and warts."
• "Clove: Clove has been investigated on Herpes simplex and hepatitis C viruses and was found to be antiviral. Some of the primary uses of clove essential oil include candida, herpes simplex, lupus . . . viral infections, and warts."
•"Eucalyptus: Eucalyptus has demonstrated an ability to inhibit the Herpes simplex virus. Some of the primary uses for eucalyptus include Influenza, Measles, Neuralgia, Neuritis, Pneumonia, respiratory viruses rhinitis, shingles, sinusitis and tuberculosis."

Under the heading, "Essential Oil for Inflammation":

• "Cancer, Autoimmune Diseases . . . Diabetes, Inflammation, Alzheimer's Disease, Neurological Diseases, Arthritis, Pulmonary Diseases"
• "Clove: . . . rheumatoid arthritis . . ."
• "Eucalyptus: . . . bronchitis, ear inflammation, iris inflammation, general inflammation, neuralgia"
• "Frankincense: Alzheimer's Disease, arthritis, cancer, inflammation . . ."
• "Geranium: Diabetes, endometriosis, osteoarthritis, rheumatoid arthritis"

• "Lavender: . ..cancer, inflammation, insomnia, pain, rheumatoid arthritis"
• "Lemongrass: Grave's Disease, Hashimoto's Disease . . ."
• "Melaleuca: Bronchitis . . . infections, inflammation"
• "Myrrh: Gum disease, hyperthyroidism, infection, skin ulcers"
• "Peppermint: Asthma, Crohn's Disease . . . Irritable Bowel Syndrome"
• "Rosemary: Arthritis, Bell's Palsy, diabetes . . . inflammation, osteoarthritis"
• "Wintergreen: Arthritic pain, bone pain, joint pain"

On social media accounts (*e.g.* Facebook, Twitter, Pinterest, and You Tube):

• In August 3, 2014 posts by dōTERRA consultant, "Mrs. Skinny Medic" to Twitter (www.twitter.com/MrsSkinnyMedic);

- "Ebola Prevention?"
- "Treating the symptoms of Ebola Virus with DoTERRA Essential Oils."
- "Many Essential Oils are highly Anti-viral. I list here a few of them those *(sic)* oils that could help prevent your contracting the Ebola virus . . .."
- The video includes claims, including the following examples:

• "On Guard is very anti-viral..."
• "Melaleuca . . . highly anti-viral"

• In June 12, 2014 posts titled, "Common Uses for Essential Oils" to the Facebook and Twitter accounts, accessible at www.facebook.com/anytimeessentials and https://twitter.com/atessentials:

- Both posts include a link to the website, www.anytimeessentials.com where disease claims can be found and where consumers can purchase products from your webpage, www.mydoterra.com/anytimeessentials.

Disease claims include, but are not limited to, the following:

- "Clary Sage: Cramps . . . Endometriosis, Estrogen Balance, Hormonal Balance, PMS, Pre-menopause"
- "Lemongrass . . . Reduce high cholesterol"
- "Rosemary Asthma, Antimicrobial, Bronchitis, Diuretic . . ."
- "Frankincense: Sciatic Pain . . . Anxiety, Depression . . . Infections"
- "Wintergreen Analgesic, Anti-Inflammatory, Joint Pain . . . Arthritis"
- "Vetiver: . . . ADD/ADHD . . . Anxiety"
- "Oregano: Antibiotic, Athlete's Foot . . . Canker Sores, Fungal Infections, Inflammation, MRSA, Staph Infections"

In a December 27, 2013 post to the Facebook account, https://www.facebook.com/EverydayEssentialOils which includes a link to where consumers can purchase your products from your www.mydoterra.com website:

- "Frankincense helps with Crohn's and digestive diseases, Heart disorders of all kinds, liver concerns . . . cirrhosis recovery . . .."
- Under the heading "Frankincense":

• "Anti-inflammatory"
• "Anti-Cancer Properties"
• "Neurological Issues"
• "Tumor Reduction"
• "Immune System Strengthener"
• "Lowers High Blood Pressure"
• "Helps Symptoms of Crohn's, Arthritis, & Epilepsy"

• In a post titled, "how to use peppermint essential oil" accessible at http://www.pinterest.com/mrsjennattaway/wellness-empress-essential-oil-education/:

- "Asthma/Congestion"
- "Autism"
- "Bacterial Infections"
- "Brain Injury"
- "Cold Sores"
- "Fever"
- "anticarcinogenic"

It is clear from the above claims that your "Melaleuca," "Oregano," "On Guard," "Clove," "Eucalyptus," "Frankincense," "Geranium," "Lavender," "Lemongrass," "Myrrh," "Peppermint," "Rosemary," "Wintergreen," "Cassia," "Clary Sage," and "Vetiver" are promoted for conditions that cause them to be drugs under section 201(g)(1)(B) of the Act because they are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Moreover, your products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of these products without approved applications violates these provisions of the Act. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

Your products are prescription drugs as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)]) for some of the claims made for them because, in light of their toxicity or other potentiality for harmful effect, the method of their use, or the collateral measures necessary to their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them.

Your dōTERRA Essential Oil products, "Melaleuca," "Oregano," "On Guard," "Clove," "Eucalyptus," "Frankincense," "Geranium," "Lavender," "Lemongrass," "Myrrh," "Peppermint," "Rosemary," "Wintergreen," "Cassia," "Clary Sage," and "Vetiver" are also misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], in that the labeling for these products fail to bear adequate directions for use for all of their

claims. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Prescription drugs can only be used safely at the direction, and under the supervision, of a licensed practitioner Therefore, it is impossible to write "adequate directions for use" for a prescription drug to be used by a layperson. As previously mentioned, these dōTERRA Essential Oil products are offered for conditions, such as ebola virus infection, that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners. Therefore, adequate directions cannot be written so that a layman can use these drugs safely for those intended uses. FDA-approved prescription drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate directions for use by a layperson (21 C.F.R. §§ 201.100(c)(2) and 201.115). Because there are no FDA-approved applications for these products, the labeling of these products fails to bear adequate directions for their intended use and, therefore the products are misbranded under section 502(f)(1) of the Act. Accordingly, the introduction or delivery for introduction into interstate commerce of your misbranded dōTERRA Essential Oil products is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. While FDA has mentioned specific dōTERRA Essential Oil products in this letter, there are drug claims being made by your consultants for a wide range o your dōTERRA Essential Oil products. As such, the cited violations in this letter should not be viewed to apply solely to the specific products mentioned in this letter. It is your responsibility to ensure that all of your products are in compliance with all requirements of the Act and federal regulations. You should take prompt action to correct the violations cited in this letter. Failure to implement lasting corrective action on violations may result in regulatory action being initiated by FDA without further notice.

We note that some of your products are marketed as dietary supplements, but are marketed for topical use. Under section 201(ff)(2)(A)(i) of the Act [21 U.S.C. § 321(ff)](2)(A)(i)], a dietary supplement is defined, among other things, as a product intended for ingestion. Topical products are not dietary supplements. In any case, the claims referenced above in this letter are drug claims, which are not suitable claims for dietary supplements. As such, whether or not they are intended for ingestion, the above-mentioned dōTERRA Essential Oil products are drugs under section 201(g)(1)(B) of the Act and not dietary supplements under section 201(ff) of the Act.

We request that you notify this office in writing within 15 working days from your receipt of this letter of the current status of your corrective actions and the specific steps you have taken to correct the noted violations. In your response, include documentation of your corrective actions. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and please include a timetable for the implementation of any remaining corrections.

If you need additional information or have questions concerning any products distributed through your website, please contact the FDA. You may respond in writing to LaTonya M. Mitchell, District Director, Denver District Office, Building 20 – Denver Federal Center, P.O. Box 25087, 6th Avenue & Kipling Street, Denver, Colorado 80225. If you have any questions concerning this letter, please contact Thomas R. Berry, PharmD, Compliance Officer, at 303-236-3028.

Sincerely,
/S/
LaTonya M. Mitchell
Denver District Director

cc:

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