




Inspections, Compliance, Enforcement, and Criminal Investigations

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Compliance Actions and Activities

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Young Living 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

Young Living
Attn: Mr. Gary Young, CEO
3125 Executive Parkway
Lehi, UT 84043

Dear Mr. Young:

This is to advise you that in August 2014 the U.S. Food and Drug Administration (FDA) reviewed websites and social media accounts (e.g., Facebook, Twitter, and Pinterest) for several Young Living essential oil consultants that your firm refers to as "Young Living distributors." FDA also reviewed a 2012-2013 product guide found on your website <http://www.youngliving.com>. Based on our review, FDA has determined that many of your Young Living Essential Oil products, such as, but not limited to, "Thieves," "Cinnamon Bark," "Oregano," "ImmuPower," "Rosemary," "Myrtle," "Sandalwood," "Eucalyptus Blue," "Peppermint," "Ylang Ylang," "Frankincense," and "Orange," are promoted for conditions that cause them to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)], because they are intended for use in the diagnosis, 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, the

marketing and distribution of your Young Living Essential Oil products without FDA-approved applications is in violation of the Act.

You market your Young Living Essential Oil products through paid consultants; your compensation plan for your consultants is explained on your website www.youngliving.com/en_US/opportunity/compensation-plan. Your consultants promote many of your Young Living Essential Oil Products for conditions such as, but not limited to, viral infections (including ebola), Parkinson's disease, autism, diabetes, hypertension, cancer, insomnia, heart disease, post-traumatic stress disorder (PTSD), dementia, and multiple sclerosis, that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners. Consumers interested in your Young Living Essential Oil products are then redirected by your consultants to your website, <http://www.youngliving.com>, to purchase your products and/or register as members (*i.e.*, consultants).^[1]

Examples of claims found on some of your consultants' websites that establish the intended use of your Young Living Essential Oils products include, but may not be limited to, the following:

On the website, www.theoildropper.com, under the heading, "Young Living Versus Ebola Virus":

- Under the subheading, "Be Prepared":
 - "Since I have become an avid Young Living essential oil user I have learned all about the anti-microbial properties of so many oils, including ANTI-VIRAL constituents in many of our essential oils."
 - "Viruses (including Ebola) are no match for Young Living Essential Oils"
- Under the subheading, "Top Oil Choices for Viruses":
 - "Top on my list is Thieves. Thieves is highly anti-microbial . . . it could help against Ebola."
 - "Ebola Virus can not live in the presence of cinnamon bark (this is in Thieves) nor Oregano." [sic]
 - "ImmuPower by Young Living would be a top choice as well. ImmuPower is a blended oil containing (oregano, clove, frankincense, ravintsara, cistus, mountain savory and hyssop). Every single one of these individual oils has anti-viral properties."

On the website, www.theoildropper.com, under the heading, "Rosemary Essential Oil by Young Living":

- "[R]egular use of rosemary essential oil may . . . help prevent diseases associated with free radicals, including cancer and heart disease."
- "Rosemary research in regards to Alzheimer's disease showed aromatherapy as a potential treatment for the cognitive (eg, memory) impairments caused by dementia."
- "Rosemary . . . has antimicrobial and antiseptic qualities than [sic] may help eliminate . . . eczema and dermatitis."

On the website, www.theoildropper.com, under the heading, "Myrtle Essential Oil Uses & Benefits":

- "Myrtle is a wonderful antiseptic . . . It has been known to protect against tetanus . . ."
- "Myrtle . . . is also beneficial for other conditions that affect the nerves such as Parkinson's, Alzheimer's . . ."
- "[M]yrtle . . . can help with sexual dysfunction issues such as impotency . . . and ED."
- "**Cancer protection**...According to a study . . . Myrtle inhibited prostate and breast cancer cells along with Sandalwood at very low concentrations. Sandalwood essential oil ranked number one for inhibiting growth of breast cancer at 98.1% and Myrtle was at 95.2%."

On the website, www.theoilessentials.com, under the heading, "Are you panicked about the Ebola Virus after watching the news this week?":

- "[T]he Ebola virus cannot survive in the presence of a therapeutic grade Cinnamon Bark and Oregano essential oil."

On the website, www.theoilessentials.com, under the heading, "Young Living August 2014 Monthly Promotion":

- Under the subheading, "Young Living Eucalyptus Blue essential oil":
 - "Eucalyptus Blue essential oil has antiviral and anti-inflammatory properties."

- Under the subheading, “Young Living Peppermint Essential Oil”:
 - o “Peppermint oil has so many more uses . . . asthma, autism, brain injury . . . Crohn’s disease . . . multiple sclerosis, paralysis . . .”

On the website, www.theoilessentials.com, under the heading, “Young Living July 2014 Monthly Promotion”:

- Under the subheading, “Ylang Ylang Essential Oil”:
 - o “Ylang Ylang is used medicinally . . . for the treatment of . . . arterial hypertension . . . diabetes . . . insomnia, heart palpitations, and tachycardia.”

On the website, <http://essentialsurvival.org>, under the heading, “Essential Oils & More to Combat Ebola Virus”:

- Under the subheading, “My Essential Oil Picks for Ebola”:
 - o “The most potent anti-viral essential oils that I have in my arsenal are **Thieves, ImmuPower** . . .”
 - o “**Thieves** oil is a blend of cinnamon, rosemary, clove, eucalyptus, and lemon oils that has been shown in university studies to obliterate bacteria and viruses, as well as mold . . .”
 - o “**Thieves oil can be . . . applied topically on the skin to help the body fight off infection** . . . If Ebola was going around in my area . . . I would apply it to my feet and armpits 2x/day or more and take it in capsules at least 2x/day for preventive purposes.”
 - o “If I were exposed to Ebola or had reason to believe I could be sick with it, I would **use some of these oils every 10 minutes for a few hours, then cut back to every hour for the rest of the first day**. Then I would use them every 2 waking hours of the day for at least a week, or longer if it was known I was sick.”

On the website, <http://essentialsurvival.org>, under the heading, “Frankincense – Medicine for Wise Men & Women”:

- Under the subheading, “Frankincense Cancer Research”:
 - o “Research shows that components of frankincense oil called boswellic acids have an anti-tumor effect on the following types of cancer cells, causing them to implode . . . Prostate cancer cells . . . Colon cancer cells . . . Cervical cancer cells . . . Bladder cancer cells . . . Leukemia cells . . . Melanoma and fibrosarcoma cells . . . Brain tumor cells.”
 - o “Boswellic acids also appear promising to help with **multiple myeloma**, and have general **anti-cancer properties**.”
- Under the subheading, “In summary, **frankincense oil**”:
 - o “Is toxic only to cancer cells (unlike chemotherapy that kills healthy cells too) . . . Causes cancer cells to implode through ‘apoptosis’, the best way for cancer cells to go . . . Shrinks tumors in preliminary research with animals . . . Helps the body heal from all types of cancer in clinical data . . . Helps to prevent cancer – using it appears to lower risk of cancer . . .”

In addition, examples of claims that establish the intended use of your Young Living Essential Oil products found on the social media accounts (e.g., Facebook, Twitter, and Pinterest) of your consultants include, but may not be limited to, the following:

On Facebook.com:

- www.facebook.com/theoil Dropper (August 11, 2014 posting) – “Be prepared for any virus that may attack! It is said that the Ebola virus can’t live in the presence of Cinnamon Oil and Oregano Oil.”
- www.facebook.com/getwellwithoils (August 9, 2014 posting) – “Oils for the Autism Spectrum! . . . Many have found a protocol of essential oils and supplements have helped ease the symptoms of autism-related issues . . .”

On Twitter.com:

- www.twitter.com/YLWaterloo (August 21, 2014 posting) – “Victory over arthritis! Use #YLPeppermint #YLPanaway and #YLFrankensence”

- www.twitter.com/Oil_Distributor (August 23, 2014 posting) – “One of the many #YoungLiving New Products the Freedom Sleep & Freedom Release kits. Help 4 Vets that suffer PTSD”

On Pinterest.com:

- www.pinterest.com/naturesezremedy/young-living-testimonials/ – “Young Living Works! Lupus Gone”
- www.pinterest.com/caricaraway/the-oil-dropper-young-living-essential-oils/ – “Young Living’s Orange. Try me for . . . Arteriosclerosis . . . Hypertension . . . Cancer . . . Insomnia . . .”
- www.pinterest.com/yloislady/heart-disease-treat-heart-disease-naturally-get-a/
 - o “Heart Disease – Treat heart disease naturally. Get a Healthy Heart with Young Living Essential oils”
 - o “Heart disease can be prevented. Learn more – www.ylscents.com/ ... #heartdisease #essentialoil”
- www.pinterest.com/pin/184225440979760087/ – “Essential Survival Daily Essential Oil Tip . . . Frankincense . . . For Alzheimer’s Disease . . .”

It is clear from the claims above that your Young Living Essential Oil products, “Thieves,” “Cinnamon Bark,” “Oregano,” “ImmuPower,” “Rosemary,” “Myrtle,” “Sandalwood,” “Eucalyptus Blue,” “Peppermint,” “Ylang Ylang,” “Frankincense,” and “Orange,” are 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, “Thieves,” “Cinnamon Bark,” “Oregano,” “ImmuPower,” “Rosemary,” “Myrtle,” “Sandalwood,” “Eucalyptus Blue,” “Peppermint,” “Ylang Ylang,” “Frankincense,” and “Orange” are also “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 the 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 the drug. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

Your products, “Thieves,” “Cinnamon Bark,” “Oregano,” “ImmuPower,” “Rosemary,” “Myrtle,” “Sandalwood,” “Eucalyptus Blue,” “Peppermint,” “Ylang Ylang,” “Frankincense,” and “Orange,” 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 it.

Your Young Living Essential Oil products, “Thieves,” “Cinnamon Bark,” “Oregano,” “ImmuPower,” “Rosemary,” “Myrtle,” “Sandalwood,” “Eucalyptus Blue,” “Peppermint,” “Ylang Ylang,” “Frankincense,” and “Orange,” 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. 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). Accordingly, 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. The introduction or delivery for introduction of a misbranded drug into interstate commerce 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 Young Living Essential Oil products in this letter, there are drug claims being made by your consultants for a wide range of your Young Living 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 Young Living Essential Oil products are marketed as dietary supplements, but are offered for topical use and/or intended for inhalation. 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 and other products that are not intended for ingestion 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 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

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[1] On your firm's registration webpage, the consultant's identification number will either pre-populate onto the registration form or consumers are asked to provide the referring consultant's identification number.

Page Last Updated: 09/24/2014

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