Long Life Unlimited 1/31/18

U.S. FOOD & DRUG ADMINISTRATION

Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237
Telephone: (513) 679-2700
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WARNING LETTER
533282

January 31, 2018

VIA UPS

Long Life Unlimited, LLC
Attn: Barbara A. Long
328 E. Kibby St.
Lima, OH 45804

4325 E. Bluelick Rd
Lima, OH 45801

Dear Ms. Long,

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.longlifeunlimited.com in January 2018 and has determined that you take orders there for your products Balance 600, D-Limonene, Rapha Remedy, Rapha Remedy w/ p73 Wild Oregano, Vitamin C, Buffered TR, Multi Forte Plus, Natural Beta Carotene, Natural Vitamin E, Omnizyme, Thymus, Selenium Chelate, Super 15, and Super B-10. The claims on your website establish that the products are drugs under section 201(g)(1)(B) and/or (g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B) and/or (g)(1)(C)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease, and/or because they are articles (other than food) intended to affect the structure or any function of the body of man or other animals. As explained further below, introducing or delivering these products for introduction into interstate commerce violates the Act. You can find the Act and FDA regulations through links on FDA's home page at **www.fda.gov (http://www.fda.gov/)**.

Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:

Balance 600

- Balance 600 can help reduce high cholesterol by ... helping reduce cardiac disease. Amino acids within Balance 600 help reduce arteriesclerosis by preventing damage to blood vessel walls and reducing the formation of dangerous lesions. Balance 600 can help reduce hypoglycemia by stabilizing and regulating blood sugar while increasing insulin levels and sensitivity."

D-Limonene

- “D-Limonene helps to successfully reduce cholesterol and dissolve gallstones. It is an anti-: fungal, microbial, parasitic, viral, and bacterial. D-Limonene is used in some cancer treatments because it is a cyclic monoterpene that induces Apoptosis (death of cancer cells). It may also inhibit tumor growth. Animals [sic] studies show activity of d-limonene against breast cancer, pancreatic, stomach, colon, skin and liver cancers. D-Limonene can also provide relief from acid reflux . . . and G.E.R.D.”
- “[D]-limonine . . . prevents cancer before it starts.”

Rapha Remedy

- “Rapha Remedy can be used as a soothing salve for treatment of the symptoms resulting from:
    - “Eczema and Rosacea
    - “Cracked, Dry, Itching and Burning Skin
    - “Dandruff
    - “Bed Sores and Sores from quadriplegic conditions
    - “Chicken Pox, Shingles and Blisters
    - “Diaper Rash
    - “Cold Sores and Canker Sores
    - “Psoriasis
    - “Dermatitis
    - “Sunburn and Peeling Skin from tanning
    - “Athlete's Foot and Nail Fungus
    - “Sore, Dry Heels. Helps soften tough, rough skin on feet
    - “Warts, Moles, Skin Tags
    - “Cuts, Bruises and Spider Veins
    - “Skin Discoloration, Brown spots (hormonal, pregnancy and liver spots)
    - “Elasticity to Scars and Skin
    - “Sagging, Wrinkled, Aging Skin
    - “Red and Blood Spots, White Spots, Sties and Dry Eye Lids
    - “Stretch Marks (also aids in prevention), Scarring, Deep cuts in cuticles and Hangnails
    - “Burns from Radiation
    - “Frost Bite and can help protect your skin from the cold weather
    - “Muscle fatigue and tension
    - “Measles, Hives and Insect Bites
    - “Jock Itch
    - “Nasal Polyps
    - “Strengthens Dry Nails”

Rapha Remedy w/ p73 Wild Oregano

- “Rapha Remedy with P73 Wild Oregano Oil can be used as a soothing salve for treatment of the symptoms resulting from:
    - “Gangrene
    - “MRSA and Staph
    - “Parasites
    - “Basal, Squamous-cell Carcinoma and Melanoma cells”
- “Rapha Remedy with P73 Wild Oregano Oil can also treat all of the same symptoms as the Original Rapha Remedy, some of which include:
    - “Eczema
    - “Cracked and itching skin
    - “Dandruff
    - “Bed sores
    - “Chicken pox
    - “Diaper rash
    - “Cold sores
    - “Psoriasis
    - “Dermatitis
    - “Sunburn
    - “Athlete's foot”

Cancer Protocol

On the webpage titled “Cancer Protocol” you list products and directions for use as part of the protocol. You suggest and provide links to the following products which are for sale on your website:

- Vitamin C, Buffered TR
- Multi Forte Plus
- Natural Beta Carotene, 25,000 IU
- Natural Vitamin E, 400 IU
- Omnizyme
- Thymus
- Selenium Chelate
- Super 15
- Super B-100

Testimonials

Your website also contains evidence of intended use in the form of personal testimonials recommending or describing the use of Balance 600 for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

- “I’m a diabetic. In June and July my blood sugar readings were between 400 and 500. My insulin was costing me $500 a month. I started taking Balance 600 and 2 months later, in October, I’ve had my first normal reading.”
- “My blood sugar level dropped from 269 to 116 after using Balance 600.”
- “Balance 600 has helped my sugar; it drops every 3 months when I go to the doctor.”

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are “new drugs” under section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). “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 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your Balance 600, Cancer Protocol, D-Limonene, Vitamin C, Buffered TR, Multi Forte Plus, Natural Beta Carotene, Natural Vitamin E, Omnizyme, Thymus, Selenium Chelate, Super 15, Super B-100, Rapha Remedy, and Rapha Remedy w/ p73 Wild Oregano products are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, your Balance 600, Cancer Protocol, D-Limonene, Vitamin C, Buffered TR, Multi Forte Plus, Natural Beta Carotene, Natural Vitamin E, Omnizyme, Thymus, Selenium Chelate, Super 15, Super B-100, Rapha Remedy, and Rapha Remedy w/ p73 Wild Oregano products fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates 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. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in enforcement action without further notice, including, without limitation, seizure and/or injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the violations noted above. Your response should include any documentation that would assist in evaluating your corrections. If you cannot complete corrective action within fifteen working days, please explain the reason for the delay and the date by which you will make the correction.

Your response should be sent to U.S. Food and Drug Administration, Stephen J. Rabe, Compliance Officer, Food and Drug Administration, at the address in the letterhead. If you have any questions with regard to this letter, please contact Mr. Rabe at 513-679-2700 extension 2163 or email at **Stephen.rabe@fda.hhs.gov (mailto:Stephen.rabe@fda.hhs.gov)**.

/S/
Kimberly L. McMillan
Acting Director, Division V
Office of Human and Animal Food Operations - East