

United States of America FEDERAL TRADE COMMISSION Southwest Region

Dama J. Brown, Regional Director Federal Trade Commission – Southwest Region 1999 Bryan Street, Suite 2150 Dallas, Texas 75201

June 2, 2020

WARNING LETTER

Via U.S. Mail

Big Sky Compounding 1600 Whitefish Stage Road, Suite #2 Kalispell, Montana 59901

Re: Unsubstantiated Claims for Coronavirus Prevention and Treatment

To Whom It May Concern:

This is to advise you that FTC staff reviewed your website at https://www.bigskycompounding.com on May 14, 2020. We have determined that you are unlawfully advertising that certain products prevent or treat Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus prevention or treatment claims on your website include the following representations made on a page titled "Coronavirus Tips COVID-19":

- You claim: "we have listed some of the supplements we carry in **bold** for immune support and whether it is a prevention or treatment option."
- You claim: "Remember 75% of deaths are caused by pre-existing conditions and weaknesses in the body. Organ failure only occurs in a body that is malnourished. When the body is weak, secondary infections such as pneumonia (Upper respiratory infections, Severe Acute Respiratory Syndrome (SARS)) are the reason for death, not the virus itself....This is an 'envelope' virus and all the principles below apply to **prevention and therapies** which should be taken seriously."
- You claim on this same page: "**Optimize Vitamin C levels** in the body... This is best to do WHEN you get sick, and take a dose every hour or two until diarrhea (which means you have plenty!). High doses are anti-viral treatment.

- Premier Research Labs **Vitamin C** is made from food and AMAZING for **prevention**.
- Vitamin C with Bioflavonoids by Thorne or our Vitamin C of the week (Ester C, Vitamin C with Quercetin) if you get sick.. [sic] Dose up every hour until diarrhea for maximizing effectiveness.
- Dr. Mercola Liposomal C is on backorder but an excellent <u>treatment</u> option as well."
- Under the heading "Remineralize the Body and Tissues to prevent and treat Viruses," you claim:
 - "If the diet is not optimal, consider optional supplementation of minerals: Take a Whole foods MultiVitamin or Mineral Replacement:
 - Innate or MegaFood One Daily MultiVitamin
 - Pure Nutrient 950 or Thorne Basic Nutrients III for a daily multivitamin
 - Tonic Alchemy Green Food and Herb Drink
 - **Trace Minerals:** Fulvic Acid trace minerals or IonBiome trace minerals in Water....
- Under the heading "Anti-Viral (Envelope Virus) <u>Prevention</u> or <u>Treatment</u> Pick ONE or TWO to keep in your medicine cabinet!" you claim:
 - "Anti-Viral Herbs to Eat or Essential oils: Lemon Balm, <u>Culinary or</u> <u>Essential Oil Herbs</u> ((Thyme, Oregano, Basil, Mint, Rosemary, Sage, Turmeric, Ginger), Thuja (Aborvitae), Frankincense (Boswellia), Tea Tree Oil/Melaleuca, Ravensara...
 - **Elderberry** 3-4 times daily for **prevention.** We have several types of Elderberry.
 - Umcka (Pelargonium sidoides) 3-4 times daily for treatment
 - **Oregacillin** has powerful anti-viral herbs and clears mucous from the lungs (oregano, cumin, sage, cinnamon, and ginger), take 1 capsule by mouth 3-4 times a day with food for <u>treatment</u>

- **Olive Leaf Extract** stops replication of the virus, stimulates phagocytosis and can be taken 3 times daily with food for <u>treatment</u>
- **St John's Wort** destroys protein encapsulates shells (envelop) of viruses (drug and estrogen interactions) for <u>treatment</u>...
- Red Marine Algae (Griffithsin) halts replication of the virus, fights SARS, supports immunity. This would also remineralize the body. Reishi Immune by PRL has some Red Algae.
- Andrographis inhibits cytokine storm to prevent ant [sic] treat early stages of viral disease at 500mg three times a day. We have this in our Cold Dx by Plantiva Formula and coming soon in Immunity by Douglas Labs.
- Licorice is anti-viral and provides adrenal support"
- Under the heading **"BEST HERBAL COMBINATIONS for <u>TREATMENT</u> Choices**" you claim:
 - **"ViraCon by Vital Nutrients** 3 capsules 3-4 times daily. Contains St. John's Wort, Licorice, Elderberry, Zinc, Berberine and more (remember to follow data on Elderberry with this virus before use)
 - Viranon by MediHerb Standard Process 2 caps twice daily. Contains St. John's Wort, Thuja, and Licorice
 - Umcka Tincture by HerbPharm 2-3 dropperfuls, 2-3 times daily"
- Under the heading "Anti-Viral Homeopathics," you claim:
 - "Combination of Influenzinum and Thymuline can be taken weekly to <u>prevent</u> flu and coronavirus (3-5 sprays once weekly). The stronger alternative to Influenzinum is Winter Tonic Plus available now!
 - **Umcka Products every 2-3** Hours work well to <u>treat</u> coronavirus and to prevent secondary respiratory infections from growing.
 - **Elderberry Umcka** has many antiviral homeopathics mixed with Elderberry for **treatment**...."
- Under the heading "Lung Infection/Mucous in the Lungs for <u>Treatment</u>," you claim:
 - "Wellness Formula by Source Naturals for <u>treatment</u> of viral and bacterial <u>lung infections</u>: 3 Tablets/6 caps 3-4x/day with FOOD for infection or 3 per day for <u>prevention</u>

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- BEST Premier Research Labs NAC (N-Acetyl Cysteine, Turmeric, Licorice, Bromelain) to reduce mucous and inflammation in the lungs 1 cap 3x/day for treatment
 - We carry **MULTIPLE NAC** supplements based on availability of the week, this is our most powerful way to reduce mucous in the lungs...
- **BEST Free the Lungs by Dragon Herbs** are Chinese Herbs to <u>reduce</u> <u>mucous and lung inflammation</u>
- **Oregacillin** has powerful anti-viral herbs and clears mucous from the lungs (oregano, cumin, sage, cinnamon, and ginger), take 1 capsule by mouth 3-4 times a day with food for <u>treatment</u>."

It is unlawful under the FTC Act, 15 U.S.C. § 41 *et seq.*, to advertise that a product or service can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims.

You are also advised to review all other claims for your products or services and immediately cease making claims that are not supported by competent and reliable scientific evidence.

Within 48 hours, please send a message to Assistant Director Jim Elliott via electronic mail at jelliott@ftc.gov describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Reid Tepfer at rtepfer@ftc.gov.

Very truly yours,

Dama J. Brown Regional Director, Southwest Region Federal Trade Commission