



April 14, 2020

VIA EMAIL

LaTonya M. Mitchell, PhD.
Denver District Director
Program Division Director
Office of Human and Animal Food Operations
Division IV West
[REDACTED]

Jason Humbert, Captain
Health Fraud Branch Chief
Division of Enforcement
Office of Regulatory Affairs
U.S. Food and Drug Administration
[REDACTED]

Re: Balance of Nature's Continued Use of Unapproved Drug Treatment Claims

Dear Dr. Mitchell and Capt. Humbert:

We write to file a complaint with the U.S. Food and Drug Administration against Balance of Nature, Inc., a Utah-based dietary supplement company founded by Dr. Douglas Howard that currently sells three supplements referred to as "Fruits," "Veggies" and "Fiber & Spice."¹ According to the website, eating three Balance of Nature "Fruits and Veggies" supplements is the equivalent of "eating more than 10 servings of a salad made with 31 different fruits and vegetables."² In recent advertising, Balance of Nature and its founder claim that taking Balance of Nature "Fruits and Veggies" supplements can prevent and help treat the coronavirus by boosting a person's immune system.

Such claims have been airing on the radio, including on The Joe Piscopo Show,³ Kevin McCullough Radio,⁴ and America First with Sebastian Gorka⁵ (all three of which are sponsored by Balance of Nature), as well as on YouTube, Twitter, and a company podcast series,⁶ among other platforms.

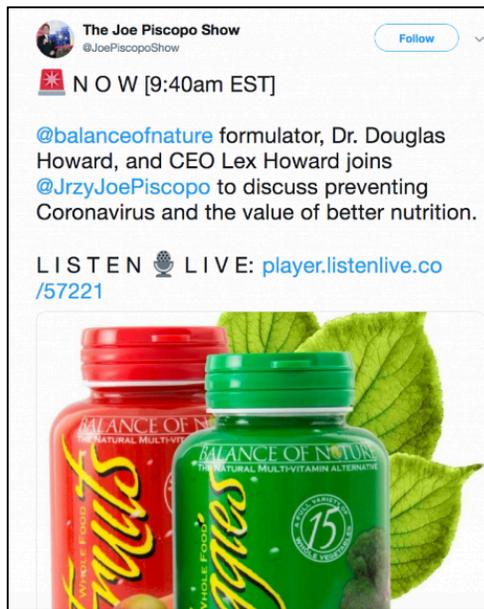
Below are some examples of such claims.

March 2, 2020, The Joe Piscopo Show, radio:⁷

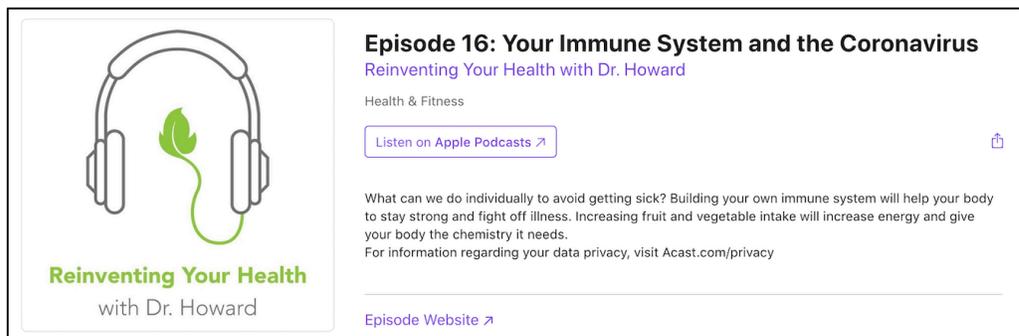
Joe Piscopo: The coronavirus, should we worry about it? ... Up our dosage of Balance of Nature? Your advice on that please.

Dr. Douglas Howard: ... First, number one, everybody relax a little bit because ... it's a cold virus, that's what it is ... build your immune system, that's all you can do ... and your body will build its own immunity to it. ... I take Balance of Nature, I keep active, and I try to stay out of any difficulties in relationships.

March 2, 2020 The Joe Piscopo Show, Twitter (since removed):⁸



March 16, 2020, Reinventing Your Health with Dr. Howard, Podcast, Episode 16, “Your Immune System and the Coronavirus”:⁹



Kevin McCullough (host): [Improving your immune system] all starts with the chemical part of what Dr. Howard was talking about, the ‘Fruits’

and the ‘Veggies’ are the foundation for that. Doc, when people try them, they’re actually combining those phytonutrients of the 31 fruits and vegetables, and what happens when they do?

Dr. Howard: Well, what it does is it literally goes to your system, it starts increasing your ability of your, of the white blood cells of your body to be able to recognize the bad predators that are coming in quicker and get rid of them faster. And so needless to say, the more you can get, the more color, the more variety, the more different types of fruits and vegetables into your system, the better. ... And they start working exponentially.

April 6, 2020, Reinventing Your Health with Dr. Howard, Podcast, Episode 19, “Is Chloroquine the Answer”:¹⁰



The image shows a podcast episode card. On the left, there is a graphic of a pair of headphones with a green leaf growing from the center. Below the graphic, the text reads "Reinventing Your Health with Dr. Howard". To the right of the graphic, the episode title "Episode 19: Is Chloroquine the Answer?" is displayed in bold, followed by the series name "Reinventing Your Health with Dr. Howard" and the category "Health & Fitness". There is a button that says "Listen on Apple Podcasts" and a share icon. Below this, a short description of the episode is provided, mentioning Chloroquine's history and the importance of prevention. At the bottom, there is a link for the "Episode Website".

Kevin McCullough (host): Doc Howard, I appreciate your constant encouragement to boost our immune systems. ... Those ‘Fruits and Veggies,’ I take them every day. I have upped my dosage the last couple of weeks because I am the one person in the house that’s been going out and having contact with the public, even at the grocery stores and stuff. So I gotta tell you, it’s working for me, I think it will work for you. 800-246-8751, you’re gonna get 35% off if you call today and free shipping on your first preferred order. It’s gonna be something you’re gonna be glad you did. Build your immune system. Fight back. You don’t have to give in to this mentality that we’re all victims to the circumstances. You can do something about that. Doc Howard, thank you as always for your time.

April 7, 2020, The Joe Piscopo Show, radio:¹¹

Now more than ever it’s time to try Balance of Nature’s ‘Fruits’ and vegetables in capsule form. Remember the best defense against any virus is your own immune system. Balance of Nature’s not like ordinary vitamins ... Strengthen your immune system today. ... You know we all make choices about cutting costs, especially now. The last things you want to cut is [sic] the things that are helping you the most. Don’t cut costs on your health. Start your journey to a stronger immune system and overall better health by calling Balance of Nature.

April 8, 2020, The Joe Piscopo Show, radio:¹²

Hey, Joe Piscopo on the radio telling you about Balance of Nature. You gotta go to balanceofnature.com. You know, Balance of Nature, it builds up your immune system, okay, that's what I always love to tell you about. Now, I can't make a clinical study, 'oh you can't say that, oh you can't, oh the FDA won't let, oh.' We need to stop, I'm telling you what works for me, and if it works for me, it's gonna work for you.

TINA.org has collected more than 20 examples of such deceptive and unsubstantiated claims, which are available at <https://www.truthinadvertising.org/balance-nature-database/>.

Balance of Nature is no stranger to the FDA as, in August 2019, the agency sent the company a warning letter because it was using unapproved drug treatment claims to mark its supplements – claims such as “Fruits and Veggies” ability to treat multiple sclerosis, diabetes and arthritis.¹³

Now, during the coronavirus pandemic,¹⁴ the company is capitalizing on the fact that there is no known treatment or vaccine for COVID-19 and marketing its “Fruits and Veggies” supplements as a way to prevent and treat coronavirus. As the above deceptive marketing examples show, Balance of Nature is taking advantage of susceptible consumers' fear of the pandemic to sell its dietary supplement. This tactic not only causes financial harm for consumers but can also have serious health consequences as well.¹⁵

As such, TINA.org strongly urges the FDA to immediately investigate the claims being made by Balance of Nature and take prompt and appropriate enforcement action.

If you have any questions, please do not hesitate to contact us.

Sincerely,



Laura Smith, Esq.
Legal Director
Truth in Advertising, Inc.



Bonnie Patten, Esq.
Executive Director
Truth in Advertising, Inc.

Cc: Dr. Douglas Howard
Chief Executive Officer
Balance of Nature, Inc.

Christopher Henderson
General Counsel
Salem Media Group, Inc.

¹ <https://www.balanceofnature.com/#/>.

² <https://www.balanceofnature.com/faq/#/>.

³ <https://am970theanswer.com/content/all/joe-piscopo>.

⁴ <https://am970theanswer.com/radioshow/578>.

⁵ <https://www.sebgorka.com/>.

⁶ <https://www.listennotes.com/podcasts/reinventing-your-health-with-dr-howard-cpe8LKYOtXk/>.

⁷ https://www.truthinadvertising.org/wp-content/uploads/2020/03/Joe-Piscopo-BoN-03_02_20-trimmed.mp4.mp4.

⁸ <https://www.truthinadvertising.org/wp-content/uploads/2020/03/Joe-Piscopo-Show-Balance-of-Nature-tweet.png>; <https://twitter.com/JoePiscopoShow/status/1234487093314887681>.

⁹ <https://www.listennotes.com/podcasts/reinventing-your/episode-16-your-immune-XY1rvDfbjLd/>.

Note that the total number of fruits and vegetables claimed to be in the Balance of Nature supplements is 31. <https://www.balanceofnature.com/product/fruits-veggies/#/>.

¹⁰ <https://www.listennotes.com/podcasts/reinventing-your/episode-19-is-chloroquine-dL4AbITcpfE/>.

¹¹ https://www.truthinadvertising.org/wp-content/uploads/2020/04/JoePiscopo-8.17-AM-4_7_20.m4a.

¹² https://www.truthinadvertising.org/wp-content/uploads/2020/04/JoePiscopo-9.18-AM-4_8_20.m4a.

¹³ August 20, 2019 FDA Warning Letter to Evig LLC dba Balance of Nature, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/evig-llc-dba-balance-nature-580888-08202019>. In response to reports that Balance of Nature received an FDA warning letter that cited “serious violations,” Dr. Howard stated, on April 3, 2020 on Kevin McCullough Radio: “That’s not true. That’s an absolute false lie statement. Every company has FDA letters.” https://www.truthinadvertising.org/wp-content/uploads/2020/04/Kevin-McCullough-04_03_20.m4a.

As of April 2020, Balance of Nature continues to make claims that its supplements can treat multiple sclerosis, among other things. See <https://www.balanceofnature.com/video/#/>.

In 2018, the National Advertising Division referred the company to the Federal Trade Commission’s attention for its use of unsubstantiated marketing claims about its dietary supplement, including that it enhances the immune system, prevents pneumonia, mitigates symptoms of multiple sclerosis, and prevents cancer. See Nov. 6, 2017 NAD Press Release, <https://ascreviews.org/balance-of-nature-inc-fails-to-respond-to-nad-inquiry-into-ad-claims-for-balance-of-nature-dietary-supplement-claims-referred-to-ftc/>. At that time, the Commission

decided not to take action. *See* June 20, 2018 FTC Letter to NAD, https://www.ftc.gov/system/files/documents/public_statements/1388262/2018-06-20_balance_of_nature_resolution_letter.pdf.

TINA.org has also alerted the FTC to the issues described in this letter.

¹⁴ As of April 2020, the coronavirus, which has caused millions of Americans to live in quarantine to avoid contracting the deadly disease, has infected more than a half a million people and claimed more than 20,000 lives in the United States.

¹⁵ This company's marketing is similar to Free Speech Systems LLC d.b.a. Infowars.com, which received a warning letter from the FDA on April 9, 2020. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/free-speech-systems-llc-dba-infowarscom-605802-04092020>.