



## **WARNING LETTER**

Date: December 2, 2020

TO: [admin@hotzemail.com](mailto:admin@hotzemail.com)  
[info@drhotze.com](mailto:info@drhotze.com)

Dr. Steven F. Hotze, MD  
Health & Wellness Center International One, L.L.C. dba Hotze Vitamins  
20214 Braidwood, Ste. 215  
Katy, Texas 77450

RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your websites at the Internet addresses [www.hotzehwc.com](http://www.hotzehwc.com) and [www.hotzevitamins.com](http://www.hotzevitamins.com) on September 10, 2020 and November 3, 2020, respectively. We also reviewed your social media websites at [www.facebook.com/Hotze-HWC/](https://www.facebook.com/Hotze-HWC/), [www.facebook.com/MyHotzeVitamins/](https://www.facebook.com/MyHotzeVitamins/), [www.twitter.com/hotzehealth.com](https://www.twitter.com/hotzehealth.com), and [www.twitter.com/HotzeVitamins/](https://www.twitter.com/HotzeVitamins/), where you direct consumers to your website [www.hotzevitamins.com](http://www.hotzevitamins.com) to purchase your products. The FDA has observed that your website [www.hotzevitamins.com](http://www.hotzevitamins.com) offers the products “Dr. Hotze’s Immune Pak with Vitamins A, B, C, D, Zinc and Probiotics” (sometimes referred to on your websites as “Dr. Hotze’s Immune Pak” or “Dr. Hotze’s Immune Pak for Adults”), “Dr. Hotze’s Kids Immune Pak,” and “Dr. Hotze’s Teen Immune Pak” for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>1</sup> in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The disease caused by the virus has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.<sup>2</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>3</sup> Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate,

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<sup>1</sup> As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

<sup>2</sup> Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>). The declaration has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx>).

<sup>3</sup> President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your websites that establish the intended use of your products, including based on statements about the purported effects of their ingredients,<sup>4</sup> and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

On your Hotze Vitamins website [[www.hotzevitamins.com](http://www.hotzevitamins.com)]:

Your blog post titled, “BACK TO SCHOOL: NEW KIDS AND TEEN IMMUNE PAKS” at [https://www.hotzevitamins.com/Back-to-School-NEW-Kids-and-Teen-Immune-Paks\\_b\\_16.html](https://www.hotzevitamins.com/Back-to-School-NEW-Kids-and-Teen-Immune-Paks_b_16.html) displays images of your products “Dr. Hotze’s Kids Immune Pak,” “Dr. Hotze’s Teen Immune Pak,” and “Dr. Hotze’s Immune Pak with Vitamins A, B, C, D, Zinc and Probiotics” and includes the following claims:

- “The time to start boosting their immune system is now . . . because of the coronavirus . . . Another way to help boost their immune system is with quality vitamins, minerals and probiotics. Take a look at the many health benefits of these supplements:”
  - “Vitamin B6 has been implicated in the regulation of immune responses that are associated with a wide range of diseases, including inflammation . . .”
  - “Research demonstrates that probiotics are safe and effective for fighting the common cold and influenza-like respiratory infections. . . .”

On your Hotze HWC website, [www.hotzehwc.com](http://www.hotzehwc.com), which directs consumers to your website [www.hotzevitamins.com](http://www.hotzevitamins.com) to purchase your products:

From your May 26, 2020, blog post titled, “Dr. Erika Schwartz on The Immune System and Coronavirus” at <https://www.hotzehwc.com/2020/05/dr-erika-schwartz-on-the-immune-system-and-coronavirus/>, which provides a transcript of Dr. Steven Hotze’s interview with Dr. Erika Schwartz and attributes the following statements to Dr. Hotze:

- “Dr. Hotze: . . . I was on Fox News on March the 15th, Sunday afternoon, on the coronavirus pandemic report. . . And I talked about the importance of vitamin A, B, C, D and Z with the probiotic, and I made my case and said, ‘Build up your immune system that’s what you need to do. If you have a healthy immune system, you’re not going to have to worry about this virus or that virus or this bacterial infection, you’re going to be healthy. And that’s what you can do and you need to do that now through . . . the vitamins you take . . .’ I mean, the lady looked at me and she goes, ‘We don’t really believe vitamins and all those things can help you with the coronavirus.’ Well of course it can.”

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<sup>4</sup> Your product labeling says your “Dr. Hotze’s Kids Immune Pak” includes Vitamin C and a probiotic and your “Dr. Hotze’s Teen Immune Pak” includes Vitamin C, Vitamin D, a probiotic blend, and Vitamin B complex.

On your Hotze Vitamins Facebook social media website [[www.facebook.com/MyHotzeVitamins/](http://www.facebook.com/MyHotzeVitamins/)] and your Hotze Health HWC Facebook social media website [[www.facebook.com/Hotze-HWC/](http://www.facebook.com/Hotze-HWC/)]:

In a July 28, 2020, post, you display graphics of your Dr. Hotze’s Kids Immune Pak and Dr. Hotze’s Teen Immune Pak products, direct consumers to your website [www.hotzevitamins.com](http://www.hotzevitamins.com) to purchase these products, and state:

- “Whether your children will be attending school in person or online, the time to start boosting their immune system is now – not only because of the coronavirus but also because of the upcoming cold and flu season.  
#coronavirus . . .”

In a May 27, 2020, post, you link to your May 2020 newsletter titled, “The Coronavirus Fraud: Power, Control and Money” at [www.hotzehwc.com/wp-content/uploads/2015/02/Hotze-Healthy-Living-Newsletter-May-2020-1.pdf](http://www.hotzehwc.com/wp-content/uploads/2015/02/Hotze-Healthy-Living-Newsletter-May-2020-1.pdf), which includes the following claims:

- “COVID-19 is not the lethal threat it’s made out to be . . . The most important thing you can do is strengthen your immune system . . . Here are my recommendations for strengthening your immune system . . .

Vitamin and mineral supplements: Daily, take vitamin A 10,000 IU, B-complex vitamins, vitamin C 1,000 mg per 25 pounds of body weight, vitamin D3 5,000–10,000 IU, zinc 30–60 mg and a potent probiotic supplement. All these nutrients enhance immune function and protect against respiratory infections. Dr. Hotze’s Immune Pak, which contains all of these in recommended doses, is available at [hotzevitamins.com](http://hotzevitamins.com) or by calling. . .”

From an April 15, 2020, post:

- “Order Dr. Hotze's Immune Pak with vitamins A, B, C, D, and Zinc – [www.hotzevitamins.com/dr-hotze-s-immune-pak.html](http://www.hotzevitamins.com/dr-hotze-s-immune-pak.html)

#covid19 #coronavirus #pandemic . . . #fightdisease . . .”

In a March 10, 2020, post:

- You state: “Have you heard Dr. Hotze talk about our new Immune Pak on the radio recently? Protect yourself from cold, flu, and even the coronavirus by boosting your immune system! . . . Order Here: [www.hotzevitamins.com/dr-hotze-s-immune-pak.html](http://www.hotzevitamins.com/dr-hotze-s-immune-pak.html)”
- Your post hyperlinks to a YouTube video you posted on March 10, 2020, in which Dr. Hotze states: “The key to preventing yourself from getting the flu or the coronavirus is having a good healthy immune system. Healthy people don’t get disease. So think about the A, B, C, D and Zs of strengthening your immune system. Vitamin A, B complex, Vitamin C, Vitamin D, and Zinc. In order to help you strengthen your immune system, I’ve devised Dr. Hotze Immune Pak. . .” [video entitled “Boost Your Immune System – Hotze Vitamins Immune Pak” at 0:04 – 0:34,

<https://youtu.be/0gzA3REXw1s>]

On your Hotze Health HWC Facebook social media website [[www.facebook.com/Hotze-HWC/](http://www.facebook.com/Hotze-HWC/)]:

In a March 25, 2020, post, you state:

- “Keep boosting your immune system. Remember I recommend Vitamins A, B, C, D, and Zinc as well as a Probiotic Blend . . . Go online hotzevitamins.com or call us on 281-646-1659 to order an Immune Pak . . . #coronavirus”

On your social media websites <http://www.twitter.com/hotzehealth/> and [www.twitter.com/HotzeVitamins/](http://www.twitter.com/HotzeVitamins/):

In an April 15, 2020, post:

- You state: “With the current #pandemic, you need a healthy immune system to prevent illness! 12 Tips to Boost Your Immune System – [hotzehwc.com/2020/04/10-way...](http://hotzehwc.com/2020/04/10-way...) #covid19 #coronavirus . . . #fightdisease . . .”
- This post links to your April 7, 2020, blog post titled, “10 Ways to Boost Your Immune System” at <https://www.hotzehwc.com/2020/04/10-ways-to-boost-your-immune-system/>, which includes the following claims:
  - A graphic on the webpage states, “Protect Yourself with DR. HOTZE’S IMMUNE PAK . . . providing the extra protection needed to help ward off infections. . .”
  - “Vitamin A is known as an anti-inflammation vitamin because of its critical role in enhancing immune function. . . it can enhance immune function and provide an enhanced defense against multiple infectious diseases.”
  - “Research shows that zinc-deficient patients had severe immune dysfunctions.”
  - “Research demonstrates that probiotics can be safe and effective in fighting the common cold and influenza-like respiratory infections. . .”

You should take immediate action to correct the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. **Within 48 hours, please send an email to [COVID-19-Task-Force-CFSAN@fda.hhs.gov](mailto:COVID-19-Task-Force-CFSAN@fda.hhs.gov)** describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to immediately correct the violations cited in this letter may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA’s website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19

related products in violation of the FD&C Act. This list can be found at <http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products>. Once you have taken corrective actions to cease the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs are subject to detention and refusal of admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your product(s) referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at [COVID-19-Task-Force-CFSAN@fda.hhs.gov](mailto:COVID-19-Task-Force-CFSAN@fda.hhs.gov).

In addition, it is unlawful under the FTC Act, 15 U.S.C. 41 et seq., to advertise that a product 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. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at [rcleland@ftc.gov](mailto:rcleland@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 Mr. Cleland at 202-326-3088.

Sincerely,

Michael W.  
Roosevelt -S

Digitally signed by Michael W.  
Roosevelt -S  
Date: 2020.12.02 07:49:14 -05'00'

On behalf of William A. Correll  
Director  
Office of Compliance  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

Sincerely,

SERENA  
VISWANATHAN

Digitally signed by SERENA  
VISWANATHAN  
Date: 2020.11.13 17:07:09  
-05'00'

Serena Viswanathan  
Acting Associate Director  
Division of Advertising Practices  
Federal Trade Commission