



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: May 4, 2020

TO: info@honeycolony.com – Maryam Henein, Honey Colony LLC
340 S. Lemon Avenue
#9590
Walnut, CA 91789

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 website at the Internet address, www.honeycolony.com, on April 22, 2020, and on April 30, 2020, respectively. We also reviewed your social media websites at www.instagram.com/honeycolonyofficial and www.twitter.com/Honeycolony, where you direct consumers to your website, www.honeycolony.com, to purchase your products. The FDA has observed that your website offers the products “Quicksilver Liposomal Vitamin C w/ Liposomal,” “Jigsaw Magnesium With SRT,” and products labeled to contain silver, including “Silver Excelsior Serum” for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ 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.² In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.³ Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, 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 and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

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

² 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>).

³ 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/>).

- “The Best Coronavirus Treatment is Prevention . . .
There may be natural ways to take control and prevent viral infections from taking hold, coronavirus included. . . .
If you want a direct antiviral effect . . . chelated silver . . . can target a wide range of viruses through several mechanisms. It is best to combine this with immune-boosting foods or supplements. . . . The aim of these supplements is to boost the immune system and provide some direct antiviral support:
 - Vitamin C 3,000 milligrams (or more) daily, in divided doses. Clinical trials of vitamin C for coronavirus patients are already underway in China. Previous research on 252 students found that 85 percent experienced relief from respiratory infections if they took high-dose vitamin C. . . .
 - Magnesium: 400 mg daily . . .
 The above antiviral protocol can go a long way in protecting yourself against both this epidemic disease and other common infections like influenza. . . .
We may not know the full story about how the coronavirus came to be, but we are not helpless.”
[from your March 13, 2020 article titled, “The Best Coronavirus Treatment is Prevention,” on your website, <https://www.honeycolony.com/article/best-coronavirus-treatment-prevention/>]
- “#covid19: From a Functional Medicine Consultant
I’m being asked what to take to bolster the immune system/fend off viruses.
@Honeycolony created a combo: Liposomal #vitaminC & chelated #silver. . . .
Liposomal Vitamin C + Silver Excelsior Immunity Boost Bundle
We created the Immunity Boost Bundle as a natural solution to do exactly what it says: keep your immune system at top performance.
honeycolony.com” [from a March 9, 2020 retweet on your Twitter social media website, www.twitter.com/Honeycolony]
- “#Covid19 Regimen . . .
That’s why i [*sic*] created @honeycolony . . .
I’ve been talking about silver for literally 6 years
Honeycolony.com/?s=silver” [from a March 11, 2020 retweet on your Twitter social media website, www.twitter.com/Honeycolony]
- “On top of proper hygiene, chelated & colloidal silver can target a wide range of viruses through several mechanisms. It is best to combine this w/ immune-boosting foods/supplements. Read our full list of #coronavirus - fighting supplements . . .
The Best Coronavirus Treatment is Prevention – HoneyColony We may not know the full story about how the coronavirus came to be, but we are not helpless. Here are some easy ways to support prevention. honeycolony.com” [from a March 14, 2020 tweet on your Twitter social media website, www.twitter.com/Honeycolony]
- “Best Coronavirus Treatment: Prevention & Antiviral Supplements
HONEYCOLONY.COM
#coronavirus #covid19
#coronavirusprevention
#covid19prevention . . .
#chelatedsilver . . .
#pandemic
#epidemic” [from a March 14 posting on your Instagram social media website, <https://www.instagram.com/p/B9t-RwOH559/>]
- “C*r*na V*r*S Is Not The Grim Reaper We Were Told . . .
honey colony

Many of the 'coronavirus fatalities' have been due to the complications of pre-existing conditions . . . that the coronavirus contributes to. . . . consider what YOU CAN DO. . . .

Stock up your reserves before we run out of the world's most potent silver brand, the chelated, 4,000PPM Silver Excelsior."

[from your emailed newsletter titled, "C*r*na V*r*S Is Not The Grim Reaper We Were Told," sent on April 16, 2020 from the email address, newsletters@honeycolony.com]

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-CDER@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 products 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-CDER@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 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,

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

Richard A. Quaresima
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission