

June 4, 2020

The Honorable Joseph J. Simons, Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Chairman Simons:

We hope this letter finds you well. Given the number of fraudulent claims proliferating in the marketplace by companies hoping to profit from public fear of the global coronavirus pandemic, the staff of the Center for Science in the Public Interest (CSPI) has been actively monitoring products and claims.

We applaud the efforts of the U.S. Federal Trade Commission (FTC), the U.S. Food and Drug Administration (FDA), and Amazon to remove supplements claiming to prevent, diagnose, or treat the respiratory disease caused by the novel coronavirus.¹ In response to these efforts, many supplements with fraudulent coronavirus or COVID-19 claims have been removed from the market.²

However, some supplements do continue to appear as results in Amazon searches for “Coronavirus Supplements”³ or “COVID Supplements”⁴ even though their marketing and labeling do not explicitly mention coronavirus or COVID-19.⁵ Separately, it is clear that certain retailers continue to prey on coronavirus fears by illegally marketing their supplements as “antiviral” products.⁶ Regardless of whether a dietary supplement’s marketing is intended to or actually does capitalize on the current pandemic, any claim that a supplement has antiviral properties is considered an impermissible disease claim by the FDA and appropriate enforcement actions should be taken against such claims. Addressing such antiviral claims is thus the necessary next step to remove products with misleading marketing during this pandemic.

This letter provides the FTC with findings regarding 46 dietary supplements marketed on Amazon with antiviral claims (*see* Appendix), which are considered impermissible disease claims by the FDA.⁷ Because these supplements’ labeling bears disease claims in violation of the Food, Drug, and Cosmetic Act (FDCA),⁸ we are sending a letter to the FDA urging it to act alongside the FTC, as the agencies have done before, in taking enforcement action against the offending manufacturers of supplements. We are also sending a letter to Amazon, requesting that the company remove these misbranded products as well as create a system to identify and prevent future “antiviral” supplements from being sold in their online and retail stores. CSPI urges the FDA, FTC, and Amazon to coordinate their efforts to remove these and future misbranded and unsafe supplements.

FTC rules state that advertisers must have a “reasonable basis for advertising claims before they are disseminated.”⁹ In deciding whether a claim is appropriately substantiated, FTC considers a variety of factors, including the type of product, the type of claim, and the “consequences of a false claim.”¹⁰ Health-related claims, such as a claim that a product will treat or cure a health condition, must be supported by reliable scientific evidence.¹¹ It is unlawful to advertise, directly or indirectly, health

claims that lack reliable scientific evidence, or to exaggerate the health benefits of products.¹² Indeed, the FTC has previously pursued enforcement actions against similar claims and products related to Zika,¹³ HIV,¹⁴ and H1N1 Influenza.¹⁵

Our market scan of products on Amazon in a search of the site using specified search terms¹⁶ on May 29, 2020, found at least 46 dietary supplements with antiviral claims in their labeling and marketing. The products found in our market scan make a large range of antiviral claims, such as “effective against an enormous array of disease causing...virus[es],”¹⁷ “virus protection,”¹⁸ and “fend off certain viruses.”¹⁹ These statements constitute disease claims, which also make the dietary supplements unapproved drugs under FDA current policy, and we are also writing the FDA a letter today.²⁰

Below are a few examples of supplement listings on Amazon that we identified as making illegal antiviral claims according to the FDA policy. We are concerned that the listings may also be unsupported by competent and reliable scientific evidence.

- Immune Support Capsules (Biotica)²¹
 - “Immune Support capsules help your immune system fight viruses and bacteria in sinus, throat and respiratory tract.”²²
- Phytobiotic Capsules²³
 - “[P]romote normal immunity against bacterial and viral infections.”²⁴
- Virus Shield²⁵
 - “It also helps with flue [sic] infections and decreases incidence and symptoms of upper respiratory tract infections.”²⁶

In addition to explicit antiviral claims, many manufacturers use supplement names, such as Viracid,²⁷ Virus Shield,²⁸ Anti-V Formula,²⁹ and Bronchial Virus Care,³⁰ that illegally imply disease claims. The FDA has said specifically that the “name of the product” is relevant to whether the labeling is making a disease claim.³¹

We are concerned that the antiviral claims found in our market scan may have been made without competent and reliable scientific evidence. We respectfully urge the FTC to immediately write letters asking companies to evaluate whether such products are making impermissible or unsubstantiated claims, as the agency has for prior viral outbreaks. Such letters should strongly recommend that these companies review their antiviral claims. As always, we welcome any questions you may have regarding our urgent and mutual interest in eliminating false and deceptive advertisements for dietary supplements.

Sincerely,

Peter Lurie, MPH, MD
President and Executive Director

Jensen N. Jose
Regulatory Counsel

Laura MacCleery
Policy Director

Notes

¹ U.S. Federal Trade Commission (FTC). *FTC, FDA warn companies making Coronavirus claims*. Mar 9, 2020. <https://www.ftc.gov/news-events/blogs/business-blog/2020/03/ftc-fda-warn-companies-making-coronavirus-claims>. Accessed May 7, 2020; FTC. *FTC Announces Latest Round of Letters Warning Companies to Cease Unsupported Claims that Their Products Can Treat or Prevent Coronavirus*. April 14, 2020. <https://www.ftc.gov/news-events/press-releases/2020/04/letters-warning-companies-cease-unsupported-coronavirus-claims>. Accessed May 7, 2020; U.S. Food and Drug Administration (FDA). *Fraudulent Coronavirus Disease 2019 (COVID-19) Products*. May 7, 2020. <https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products>. Accessed May 7, 2020; US Immigration and Custom Enforcement (ICE). *HSI partners with Pfizer, 3M, Citi, Alibaba, Amazon, Merck to protect consumers against COVID-19-related fraud*. May 5, 2020. <https://www.ice.gov/news/releases/hsi-partners-pfizer-3m-citi-alibaba-amazon-merck-protect-consumers-against-covid-19>. Accessed May 6, 2020. (“‘Since the beginning of the COVID-19 crisis, Amazon has proactively stopped more than 6.5 million products with inaccurate claims, removed over 1 million offers for suspected price gouging, suspended more than 10,000 selling accounts for suspected price gouging and referred the most egregious offenders to federal and state law enforcement across the country. Amazon welcomes HSI’s partnership in holding counterfeiters and bad actors accountable, and we look forward to building on our long-standing relationship to protect customers and ensure a trusted shopping experience,’ said Dharmesh Mehta, Amazon vice president, customer trust and partner support.”).

² *Id.*

³ Amazon. Search result for “*Coronavirus Supplements*”:
https://www.amazon.com/s?k=coronavirus+supplements&ref=nb_sb_noss_1. Accessed May 7, 2020.

⁴ Amazon. Search result for “*COVID Supplements*”:
https://www.amazon.com/s?k=COVID+supplements&ref=nb_sb_noss_2. Accessed May 7, 2020.

⁵ Our scan of Amazon’s tagging and seller policies indicates that some sellers may be suggesting these tags for searches, while in other situations, it could be that the search algorithm is suggesting products based on prior user behavior.

⁶ There is no FDA-approved treatment for COVID-19. The only authorized product is remdesivir, for which there is some randomized, controlled data, but even that is only available through a special procedure called an Emergency Use Authorization.

⁷ See FDA. *Small Entity Compliance Guide on Structure/Function Claims*. January 9, 2002. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims>. Accessed May 4, 2020; 65 Fed. Reg. 1,000.

⁸ See 21 U.S.C. §§ 321(p), 331(d), 355(a); 21 C.F.R 101.93(g)(2)(v); See, e.g., U.S. Food and Drug Administration. *Warning Letter: NRP Organics Ltd*. April 9, 2020. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/nrp-organics-ltd-606066-04082020>. Accessed April 12, 2020. (Concluding that claims, such as “PROTECT[S] YOU, AND THE ONES YOU LOVE WITH HUMIC AND FULVIC ANTIVIRUS!” are disease claims); See also, U.S. Food and Drug Administration. *Warning Letter: Young Living*. September 22, 2014. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/young-living-09222014>. Accessed May 4, 2020. (Concluding that claims, such as “potent anti-viral essential oils,” are disease claims).

⁹ U.S. Federal Trade Commission (FTC). *FTC Policy Statement Regarding Advertising Substantiation*. November 23, 1984. <https://www.ftc.gov/public-statements/1984/11/ftc-policy-statement-regarding-advertising-substantiation>. Accessed May 5, 2020.

¹⁰ FTC. *Dietary Supplements: An Advertising Guide for Industry*. April 2001. <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>. Accessed May 5, 2020.

¹¹ *Id.*

¹² 15 U.S.C. § 45(a) (barring unfair or deceptive acts or practices); see also *POM Wonderful LLC v. FTC*, No. 13-1060 (D.C. Cir. 2015) (The FTC can require substantiation of claims).

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- ¹³ FTC. *FTC Sends Warning Letters to Online Sellers Making Zika Virus-Protection Claims*. August 5, 2016. <https://www.ftc.gov/news-events/press-releases/2016/08/ftc-sends-warning-letters-online-sellers-making-zika-virus>. Accessed May 11, 2020.
- ¹⁴ FTC. *FTC and FDA Warn Consumers About Ineffective and Unapproved HIV Test Kits*. November 17, 1999. <https://www.ftc.gov/news-events/press-releases/1999/11/ftc-and-fda-warn-consumers-about-ineffective-and-unapproved-hiv>. Accessed May 11, 2020.
- ¹⁵ FTC. *FTC Warns Internet Peddlers that Marketing Unproven H1N1 Flu Products May Be Illegal*. November 16, 2009. <https://www.ftc.gov/news-events/press-releases/2009/11/ftc-warns-internet-peddlers-marketing-unproven-h1n1-flu-products>. Accessed May 11, 2020.
- ¹⁶ On April 23, 2020, CSPI staff searched Amazon for “virus supplement,” “antiviral supplement,” and “influenza supplement” and selected the first 50 dietary supplements found with antiviral claims. A review of the findings conducted on May 29, 2020, found that one supplement had removed its antiviral statements from its listing and three others were no longer listed. Due to constraints on time and resources, our market scan was limited to the 46 supplements listed in the Appendix; however, CSPI believes there are significantly more dietary supplements with antiviral claims listed on Amazon.
- ¹⁷ Results RNA. Product listing: *ACS 200 Advanced Cellular Silver*. <https://www.amazon.com/Results-RNA-Colloidal-Strength-Effective/dp/B0058HX4K8>. Accessed May 4, 2020.
- ¹⁸ Zeropoint Technologies. Product listing: *EMF Protect*. <https://www.amazon.com/Defense-Supplement-Supplements-Formulated-Protection/dp/B07XG3P1FL>. Accessed May 4, 2020.
- ¹⁹ Vibrant Health. Product Listing: *Gigartina Red Marine Algae*. <https://www.amazon.com/Vibrant-Health-Gigartina-Function-Vegetarian/dp/B00028OWM2>. Accessed May 4, 2020.
- ²⁰ FDA. *Questions and Answers on Dietary Supplements*. July 22, 2019. <https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements>. Accessed May 26, 2020. (Noting that a product sold as a dietary supplement and promoted on its labeling—which includes the label as well as accompanying material that is used by a manufacturer to promote and market a specific product—as a treatment, prevention or cure for a specific disease or condition would be considered an unapproved and thus illegal drug.)
- ²¹ Biotica. Product Listing: *Immune Support Capsules*. <https://www.amazon.com/Immune-Support-Capsules-Elderberry-Antioxidants/dp/B085XP66RZ>. Accessed May 4, 2020.
- ²² *Id.*
- ²³ Wise Woman Herbals. Product Listing: *Phytobiotic*. <https://www.amazon.com/Wise-Woman-Herbals-Phytobiotic-Capsules/dp/B005546LFY>. Accessed May 5, 2020.
- ²⁴ *Id.*
- ²⁵ Biomsify. Product Listing: *Virus Shield*. <https://www.amazon.com/Booster-Clinically-Immunobiotics-Immunity-Immunity-Immune/dp/B087JZJL1Y>. Accessed May 5, 2020.
- ²⁶ *Id.*
- ²⁷ Ortho. Product Listing: *Viracid 60 Capsules*. <https://www.amazon.com/Ortho-Viracid-60-Capsules/dp/B00AED8G68>. Accessed May 26, 2020.
- ²⁸ Biomsify. Product Listing: *Virus Shield*. <https://www.amazon.com/Booster-Clinically-Immunobiotics-Immunity-Immunity-Immune/dp/B087JZJL1Y>. Accessed May 5, 2020.
- ²⁹ Natural Factors. Product Listing: *Anti-V Formula*. <https://www.amazon.com/Natural-Factors-Formula-Echinamide-Support/dp/B000OQ8PKM>. Accessed May 5, 2020.
- ³⁰ Secrets of the Tribe. Product Listing: *Bronchial Virus Care*. <https://www.amazon.com/Bronchial-Alcohol-Free-Echinacea-Umckaloabo-Supplement/dp/B06ZZ6YWS8>. Accessed May 5, 2020.
- ³¹ 21 C.F.R. 101.93(g)(2)(iv)(A).