

June 4, 2020

The Honorable Stephen Hahn, Commissioner
and
Steven Tave, Director
Office of Dietary Supplement Programs
and
Janet Woodcock, Director
Center for Drug Evaluation and Research
and
Patrizia Cavazzoni, Deputy Center Director for Operations
Center for Drug Evaluation and Research

Food and Drug Administration
10001 New Hampshire Ave
Hillandale Bldg., 4th Floor
Silver Spring, MD 20993
and

10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn, Director Tave, Director Woodcock, and Deputy Center Director Cavazzoni:

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. Food and Drug Administration (FDA), the U.S. Federal Trade Commission (FTC), 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

It is clear that certain retailers continue to prey on coronavirus fears by illegally marketing their supplements as “antiviral” products. 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 FDA with findings regarding 46 dietary supplements marketed on Amazon with antiviral claims (*See Appendix*). CSPI urges the FDA to issue warning letters and prohibit the sale of these products, which, by making these antiviral claims, are being marketed as unapproved and/or misbranded drugs under the Food, Drug, and Cosmetic Act (FDCA).³

We are sending a similar letter to the FTC, urging that it act alongside the FDA, as the agencies have done before, to pursue legal actions against manufacturers of supplements. We are sending a letter to Amazon as well, requesting that the company remove these misbranded products and create a system to identify and prevent future “antiviral” supplements from being sold in their online and retail stores. We urge the FDA, FTC, and Amazon to coordinate their efforts to remove these and future misbranded supplements.

Our market scan of products on Amazon searched the site using specified search terms⁴ on May 29, 2020, and 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],”⁵ “virus protection,”⁶ and “fend off certain viruses.”⁷ These statements constitute disease claims, which make the dietary supplements unapproved drugs.⁸

According to the FDA’s guidance and final rule on structure and function claims, any claim that a supplement has antiviral properties is a disease claim.⁹ Dietary supplements marketed to diagnose, mitigate, treat, cure, or prevent a disease—such as diseases caused by a viral infection—are considered new drugs and may be legally sold only if they are FDA-approved as drugs.¹⁰ Although manufacturers are allowed to make structure and function claims (as long as they have adequate substantiation), such as “boosts immunity,” companies *cannot* make claims that a supplement supports the prevention or treatment of a specific disease, such as “boosts immunity *against viruses*.”¹¹

Specifically, the FDA’s final rule and guidance on structure and function claims describes certain statements (such as “antiviral” and “supports the body’s antiviral capabilities”) as clear examples that identify “a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease”¹² and/or a product that “has a role in the body’s response to a disease or to a vector of disease.”¹³ Therefore, supplements that make claims to prevent or treat viral infections are disease claims.¹⁴ In particular, the agency indicated as long ago as 2002 that “[c]ertain product class names are so strongly associated with treating and preventing diseases that claiming membership in the product class constitutes a disease claim,”¹⁵ and went on to name “antivirals” specifically as such a product class.

Supplements with antiviral claims are worthy of the FDA’s urgent attention due to the global outbreak of respiratory disease caused by the novel coronavirus. Recently issued FDA enforcement letters acknowledge that this is a focus of the FDA’s current activities, stating that “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.”¹⁶ We also note that some supplements do continue to appear as results in Amazon searches for “Coronavirus Supplements”¹⁷ or “COVID Supplements”¹⁸ even though their marketing and labeling do not explicitly mention coronavirus or COVID-19.¹⁹

The unapproved antiviral marketing of these and similar products preys upon the public anxiety fostered by the coronavirus pandemic. These claims should make enforcement a higher priority for the FDA, as consumers who fall victim to this marketing are purchasing unapproved products to prevent the spread of viruses,²⁰ may have compromised immune systems they are trying to treat,²¹ may rely on these claims to forgo clinically proven prevention and antiviral measures such as social distancing or personal protective equipment, or may delay a trip for needed medical care at a hospital or clinic.²² We urge the FDA to protect these vulnerable populations, take action against companies making unsafe supplement claims, and ultimately help curb the spread of coronavirus and future pandemics to the extent that use of these products supplants proven effective measures like handwashing or social distancing.

Below are a few examples of the explicit and implied antiviral and disease claims we identified.

- Immune Support Capsules (Biotica)²³
 - “Immune Support capsules help your immune system fight viruses and bacteria in sinus, throat and respiratory tract.”²⁴
- Phytobiotic Capsules²⁵
 - “[P]romote normal immunity against bacterial and viral infections.”²⁶
- Virus Shield²⁷
 - “It also helps with flue [sic] infections and decreases incidence and symptoms of upper respiratory tract infections.”²⁸

In addition to explicit antiviral claims, many manufacturers use supplement names, such as Viracid,²⁹ Virus Shield,³⁰ Anti-V Formula,³¹ and Bronchial Virus Care,³² that illegally imply disease claims. The agency has stated specifically that the “name of the product” is relevant to whether the labeling is making a disease claim.³³

We respectfully urge the FDA to immediately issue warning letters and bring other enforcement actions to require cessation of sales of these antiviral supplements, as well as other such products, and to allow inspectors to seize the products. 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,

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Laura MacCleery
Policy Director
Center for Science in the Public Interest

Jensen N. Jose
Regulatory Counsel
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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 Agency guidance provides that: “A claim that a dietary supplement fights disease or enhances disease-fighting functions of the body is a disease claim. Under this criterion, context and specificity are important. Claims such as ‘supports the body’s ability to resist infection’ and ‘supports the body’s antiviral capabilities’ are disease claims because the context of the claim is limited to the disease prevention and treatment capabilities. However, a claim that a product ‘supports the immune system’ is not specific enough to imply prevention of disease because the immune system has both structure/function and disease fighting roles. A general claim of this type doesn’t specifically focus the intended use of the product on the disease aspect of the system’s function (*emphasis added*).” 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.

⁴ 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.

⁵ Results RNA. Product listing: *ACS 200 Advanced Cellular Silver*. <https://www.amazon.com/Results-RNA-Colloidal-Strength-Effective/dp/B0058HX4K8>. Accessed May 4, 2020.

⁶ Zerpoint Technologies. Product listing: *EMF Protect*. <https://www.amazon.com/Defense-Supplement-Supplements-Formulated-Protection/dp/B07XG3P1FL>. Accessed May 4, 2020.

⁷ Vibrant Health. Product Listing: *Gigartina Red Marine Algae*. <https://www.amazon.com/Vibrant-Health-Gigartina-Function-Vegetarian/dp/B00028OWM2>. Accessed May 4, 2020.

⁸ 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 illegal drug.)

⁹ 65 Fed. Reg. 1,000 (January 6, 2000); 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.

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- ¹⁰ 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).
- ¹¹ 65 Fed. Reg. 1,000 (January 6, 2000); 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.
- ¹² 65 Fed. Reg. at 1,026 (Section N of the rule’s preamble uses “antiviral” as an example of a class name that would imply disease treatment or prevention).
- ¹³ 65 Fed. Reg. at 1,028 (Section Q of the rule’s preamble uses examples, such as “supports the body’s antiviral capabilities” or “supports the body’s ability to resist infection,” as a disease claim, specifically a claim that the product has a role in the body’s response to a disease or to a vector of disease); 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.
- ¹⁴ 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.
- ¹⁵ *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.
- ¹⁶ *See, e.g.* FDA. *Warning Letter: NRP Organics Ltd.* <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/nrp-organics-ltd-606066-04082020>. Accessed April 12, 2020.
- ¹⁷ Amazon. Search result for “Coronavirus Supplements”: https://www.amazon.com/s?k=coronavirus+supplements&ref=nb_sb_noss_1. Accessed May 7, 2020.
- ¹⁸ Amazon. Search result for “COVID Supplements”: https://www.amazon.com/s?k=COVID+supplements&ref=nb_sb_noss_2. Accessed May 7, 2020.
- ¹⁹ 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.
- ²⁰ U.S. Food and Drug Administration. *Market Unapproved Drugs- Compliance Policy Guide.* 2011; Sec 440.100. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketed-unapproved-drugs-compliance-policy-guide>. Accessed March 4, 2020 (lists drugs that lack evidence of effectiveness as a higher priority for enforcement actions).
- ²¹ *Id.* at 4 (lists drugs with potentially direct and indirect health threats as a higher priority for enforcement actions).
- ²² *Id.* at 4 (lists drugs that present direct challenges to the new drug approval and OTC drugs as a higher priority for enforcement actions).
- ²³ Biotica. Product Listing: *Immune Support Capsules.* <https://www.amazon.com/Immune-Support-Capsules-Elderberry-Antioxidants/dp/B085XP66RZ>. Accessed May 4, 2020.
- ²⁴ *Id.*
- ²⁵ Wise Woman Herbals. Product Listing: *Phytobiotic.* <https://www.amazon.com/Wise-Woman-Herbals-Phytobiotic-Capsules/dp/B005546LFY>. Accessed May 5, 2020.
- ²⁶ *Id.*
- ²⁷ Biomsify. Product Listing: *Virus Shield.* <https://www.amazon.com/Booster-Clinically-Immunobiotics-Immunity-Immunity-Immune/dp/B087JZJL1Y>. Accessed May 5, 2020.
- ²⁸ *Id.*

²⁹ Ortho. Product Listing: *Viracid 60 Capsules*. <https://www.amazon.com/Ortho-Viracid-60-Capsules/dp/B00AED8G68>. Accessed May 26, 2020.

³⁰ Biomsify. Product Listing: *Virus Shield*. <https://www.amazon.com/Booster-Clinically-Immunobiotics-Immunity-Immunity-Immune/dp/B087JZJL1Y>. Accessed May 5, 2020.

³¹ Natural Factors. Product Listing: *Anti-V Formula*. <https://www.amazon.com/Natural-Factors-Formula-Echinamide-Support/dp/B000OQ8PKM>. Accessed May 5, 2020.

³² 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.

³³ 21 C.F.R. 101.93(g)(2)(iv)(A).