



**FDA U.S. FOOD & DRUG
ADMINISTRATION**



WARNING LETTER

Date: November 2, 2020

TO: jhall@novabay.com
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NovaBay Pharmaceuticals, Inc.
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CC: regulatory-inquiries@amazon.com

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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 <https://novabay.com>, <https://avenova.com> and <https://saniteyesmore.com> on September 22-24, 2020, and October 27, 2020, respectively. We also reviewed your social media websites at <https://www.facebook.com/AvenovaEyeCare/> and <https://twitter.com/AvenovaEyeCare>, where you direct consumers to your website, <https://www.avenova.com>, to purchase your products. Additionally, your websites direct consumers to purchase your products through your storefronts and product listings on <https://www.amazon.com> and <https://www.walmart.com>. We also reviewed your promotional material for your products, where you direct consumers to your websites, <https://avenova.com> and <https://saniteyesmore.com>. The FDA has observed that your websites offer AVENOVA[®] ANTIMICROBIAL LID & LASH SOLUTION, PURE HYPOCHLOROUS ACID, 0.01%, 20 ml (also referred to as Antimicrobial Avenova Direct 20 ml Spray Solution and Antimicrobial All-Natural Facial Spray) for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people. Based on our review, this product is an unapproved new drug 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, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product 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

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 II, 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

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 product and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

- “AVENOVA USE FOR COVID-19[,] Avenova now provides an added layer of protection against the current coronavirus. It has been proven, from an independent third-party laboratory study, that its proprietary formulation of pure hypochlorous acid, kills SARS-CoV-2. Results at 60 seconds prove Avenova’s [sic] ability to fully inactivate the virus. If you have, or think you have, airborne respiratory droplets on your face, Avenova can be used as a facial mist & sprayed directly on your skin (eyes, nose, outside of your mouth) to kill the live virus. It is safe on children and can be sprayed any number of times, at any point after coming into contact.” [from your website <https://novabay.com/products/avenova/>]
- “NovaBay Pharmaceuticals Announces Laboratory Results Confirm Avenova Kills SARS-CoV-2 (COVID-19 VIRUS) . . . ‘Since Avenova’s inception, we have known it to be a powerful antimicrobial spray solution, effective against all types of pathogens, including a wide variety of viruses . . . Now we have results from a highly reputable independent laboratory confirming Avenova kills the coronavirus that causes COVID-19,’ said Justin Hall, Novabay CEO. . . . ‘Avenova, formulated with our pure, FDA-cleared hypochlorous acid, is completely non-toxic and is safe for use on all skin surfaces, including delicate facial skin around eyes, nose and mouth.’” [from your July 13, 2020 press release on your website <https://avenova.com/novabay-laboratory-results-confirm-avenova-kills-covid-19-virus/>]
- “Elevate Your Mask and Saniteyes More.™ Safely sanitize the skin around your eyes and face with Avenova - our FDA cleared, antimicrobial, all-natural spray. Add a layer of protection to keep yourself and your family safe during the pandemic . . . Avenova is lab tested and clinically proven to be the most effective antimicrobial lid & lash solution available with or without a prescription. Now, recent results from an independent laboratory confirm Avenova kills the coronavirus that causes COVID-19. [from your website <https://saniteyesmore.com>]
- Your Antimicrobial Avenova Direct 20 ml Spray Solution product listing on your website, <https://patients.avenova.com/avenova-direct-20ml-eyelid-eyelashes-for-dry-eye-solution/>, embeds reviews from your listing on Amazon.com. These reviews include, but may not be limited to, the following:
 - “Covid killer, great multipurpose eye care product[,] The added benefit of knowing this has shown in 3rd party lab tests to kill covid 19 makes this a no brainer purchase. Worth every penny considering the precautions were already taking and myself personally being prone to wiping my eyes without really thinking about it” [from a September 4, 2020 review]

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.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

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/>).

- “Excellent Eye Care plus Covid killer[,] This is just an amazing product. I use it for my general eye care. . . . So although I use it mainly for general eye care, I've started using it as a covid precaution. When I'm out with my kids and we're in a public area where may have been covid in the air . . . a little spritz on the face for each of use when we're back in the car. Kids think it's fun . . . brings me comfort. I just think it's a good product. Take care of your eyes...and stay safe!” [from a September 2, 2020 review]
- “Facial Sanitizer against Covid19 that resolves itchy eyes . . . In addition, this product also has been shown to kill the COVID19 virus on contact, so I also use this as a facial sanitizer. Great Product!” [from an August 19, 2020 review]
- “Covid Killing facial spray[,] With two little kids who can be pretty close to other children this is a great way to add more confidence they are safe from Covid. Spray it and let it do it's [sic] job on their faces and hands” [from an August 15, 2020 review]
- “Avenova – powerful enough to kill the COVID-19 virus, but gentle enough for your face. Since Avenova’s inception, we have known Avenova to be a powerful antimicrobial spray solution for the eyes, effective against a wide variety of pathogens including viruses, bacteria, and fungi. Now we have results from a highly reputable independent laboratory confirming Avenova kills the coronavirus that causes COVID-19 . . . #covid19resources #covid19news #covid19 #covid19response #coronaawareness #coronaprevention #covid_19” [from your August 7, 2020 post on your Facebook social media website <https://www.facebook.com/AvenovaEyeCare/>]
- “Avenova Eye Care . . . More and more medical professionals are supporting the use of Avenova for their patients and supporting the efficacy in Avenova’s proven ability to kill the coronavirus that causes COVID-19.” Accompanied by a video graphic with the text “Preliminary trials have surfaced for a spray that protects against Covid-19.” [from your August 12, 2020 post on your Twitter social media website <https://twitter.com/AvenovaEyeCare>]

On your promotional mailer:

- “SANITeyesMORE™[,] Safely sanitize the skin around your eyes and face with Avenova . . . Strong enough to kill CORONAVIRUS, yet gentle enough for your skin . . . Avenova.com | Saniteyesmore.com” accompanied by a graphic display of your AVENOVA® ANTIMICROBIAL LID & LASH SOLUTION, PURE HYPOCHLOROUS ACID, 0.01%, 20 ml.

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 product 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 product is 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 referenced above to be an unapproved and misbranded product 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 product identified above. Thus, any coronavirus-related prevention or treatment claims regarding such product 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,

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