

## WARNING LETTER

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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<sup>®</sup> 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-19<sup>1</sup> 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).

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, 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:

- x “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/>]
- x “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/>]
- x “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>]
- x 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:
  - o “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]

- o “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]
- o “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]
- o “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]
- x “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/>]
- x “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:

- x “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 claim e 8e.8 ( )Td FDA.6.6 (oA7 (-)TjT)-13.6 (l)-9.-3.3 ( ).( 2)-3.3 (0)-3.32 (l)2.6 ( )11.2 (L)-3.3 (i)2.7 (i)2..6 (

