WARNING LETTER

Phoenix Biotechnology, Inc.

MARCS-CMS 612178 — DECEMBER 15, 2020

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Lou Kost, Jr., Theresa Gallagher Obiso

Acting CEO, CEO

Phoenix Biotechnology, Inc.

Avila Herbals, LLC

8626 Tesoro Dr.
Suite 801
San Antonio, TX 78217
United States

info@phoenixbiotechnology.com (mailto:info@phoenixbiotechnology.com)

help@avilaherbals.com (mailto:help@avilaherbals.com)

Issuing Office:

CDER Office of Compliance

United States

Lou Kost, Jr., Acting CEO
Phoenix Biotechnology, Inc.
8626 Tesoro Dr., Suite 801
San Antonio, TX 78217
info@phoenixbiotechnology.com (mailto:info@phoenixbiotechnology.com)

Theresa Gallagher Obiso, CEO
Avila Herbals, LLC
4025 Childress Rd.
Christiansburg, VA 24073
help@avilaherbals.com (mailto:help@avilaherbals.com)

RE: 612178

Dear Mr. Kost and Ms. Obiso:

This is to advise you that the United States Food and Drug Administration (FDA) has reviewed Phoenix Biotechnology's website at the Internet address http://www.phoenixbiotechnology.com/, and Avila Herbals LLC's websites at the Internet addresses https://myoleander.com/ and https://avilaherbals.com in December 2020. The website https://avilaherbals.com directs consumers to the website https://myoleander.com, which offers for sale "Oleander 4X." We have also reviewed your respective social media websites at https://twitter.com/PhoenixBioInc[1] and https://twitter.com/AvilaHerbals, where you direct consumers to the website https://myoleander.com/ to purchase your "Oleander 4X" product. The FDA has observed that Avila Herbals, LLC's website https://myoleander.com/ offers "Oleander 4X," a product labeled to contain oleander, for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19[2] and other conditions in people. While reviewing the website https://avilaherbals.com, FDA observed that Avila Herbals, LLC states that it "partnered with Phoenix Biotechnology to make . . . Oleander 4X."[3] In addition, the product label of "Oleander 4X" states that the product is manufactured by Avila Herbals, LLC for Phoenix Biotechnology, Inc. and lists the website https://www.phoenixbiotechnology.com. Based on our review, "Oleander 4X" 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). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. 331(d).

Your "Oleander 4X" product is especially concerning from a public health perspective because it claims to mitigate, prevent, treat, diagnose or cure serious and/or life-threatening conditions such as COVID-19. 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.[4] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[5] 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 a product that is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 and other conditions in people. We request that you take immediate action to cease the sale of this unapproved new drug.

Some examples of claims on your product label and websites, establishing the intended uses of your "Oleander 4X" product and misleadingly representing it as safe and/or effective for the treatment or prevention of COVID-19 or other conditions include:

On the website http://www.phoenixbiotechnology.com/PBIAnswerToCovid19.php:

- "AN ALL-AMERICAN NATURAL COMPOUND TO CONTEND WITH THE COVID-19 PANDEMIC[,] A Promising Response to the Coronavirus-2019 Threat[,] Proposing an entirely U.S.-developed, -sourced and -manufactured treatment for "envelope viruses" – including Coronavirus-2019 (COVID-19) – that can be available in great scale now at a low price-point.

San Antonio-based **Phoenix Biotechnology, Inc.** (PBI) has identified and developed a product extracted from Nerium oleander, a naturally occurring American plant. An active compound from this plant is called oleandrin. PBI's research to date suggests that the extract **prevents key viruses from correctly forming their protective "envelope",** rendering the virus progeny non-infective; the virus is then unable to overwhelm the host and its ability to spread itself is severely impaired. In this way, **oleandrin** may help "flatten the curve" and curtail the pandemic. Due to its efficacy against the viral envelope, it is considered a platform solution with wide-spectrum applicability to address **multiple viral pathogens and their mutations**" (bold text in original).

On the website https://avilaherbals.com/:

- "We are naturally inquisitive scientists, and so we continually experiment with new formulae to develop exciting breakthroughs. When the coronavirus pandemic hit the start of 2020, we knew we couldn't sit by without investigating possible avenues that might help the world overcome this devastating virus. We've partnered with Phoenix Biotechnology to make a homeopathic medicine called Oleander 4X." Below this appears a button that hyperlinks to the website myoleander.com with the text "Visit Myoleander.com" followed by "We felt that in our farm we could potentially develop something that could help turn the tide against our invisible enemy – and we did just that."

On Phoenix Biotechnology's social media website https://twitter.com/PhoenixBioInc:

- In a November 19, 2020 post, you state: "What we've been trying to tell everyone since March. This stuff works. myoleander.com #COVID19" . . . See opportunities for #botanical to not only treat #COVID19 but to also prevent #SARSCoV2 #infection."

- In a September 11, 2020 post, you state: "Precisely. We do not pretend to be experts on all essential oils but, have certainly become experts in the safe use of oleandrin to combat a number of viruses. But cheap, effective, natural remedies do not fill the pockets of those not interested in a cure, only a treatment." accompanied by an embedded Tweet dated September 11 stating "And Eucalyptus citriodora essential oil has been shown to disable Covid-19. We've known that Eucalyptus is effective for colds (coronaviuses) [*sic*] for centuries. Why are we not using these effective agents in all healthcare settings etc?"

- In an additional September 11, 2020 post, you state: "Thanks @HegKong for the mention. It is truly shocking we still have not received an IND number on something that has proven to be more efficacious than the 53,000+ potential CV19 treatments tested at UTMB. The science is there. The safety is proven." accompanied by an embedded Tweet dated September 11 stating "New potential natural treatment for COVID-19 derived from the Oleander plant proposed."

- In an August 25, 2020 post, you state: "FACT: Our proposed product contains a patented botanical extract from the Nerium oleander plant. A related PBI botanical extract has already undergone Phase I & Phase II human safety trials for an oncology application. #COVID19"

On Avila Herbals' social media website https://twitter.com/AvilaHerbals:

- In a November 24, 2020 post, you state: "Oleander 4X is a homeopathic remedy for flu-like symptoms. . . . NOW AVAILABLE FOR PURCHASE Oleander 4X is an OTC homeopathic . . . myoleander.com"

On the product label:

- "Temporary relief of symptoms of fever, aches and pains associated with flu, colds, and respiratory distress of flu-like symptoms. . . "
- "Purpose[,] Flu symptoms"

On the website https://myoleander.com:

- "Oleander-4X is an all-natural homeopathic drug, which is a unique botanical extract from the leaves of the oleander plant (*Nerium oleander*). Oleander 4X provides temporary relief of flu symptoms, such as muscle or body aches, headaches, chills and fever, cough, and congestion."

The above claims for your "Oleander 4X" product demonstrate that it is a drug, as defined by section 201(g) of the FD&C Act, 21 U.S.C. 321(g), because it is intended to cure, mitigate, treat, or prevent disease. Moreover, this product is a "new drug," as defined by section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because it is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. Under section 505(a) of the FD&C Act, 21 U.S.C. 355(a), new drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA unless they are over-the-counter (OTC) drugs lawfully marketed under section 505G of the FD&C Act (which is not the case for this product). No approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for this product. Accordingly, the introduction or delivery for introduction into interstate commerce of this product violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

We recognize that you have recently begun marketing "Oleander 4X," which you market as a homeopathic drug. Under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), the term "drug" includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drug products are subject to the same statutory requirements as other drugs; nothing in the FD&C Act exempts homeopathic drugs from any of the requirements related to adulteration, misbranding, or approval.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed product. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to address the violations cited in this letter. Failure to promptly address these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within 48 hours of receipt of this letter, please notify this office in writing of the specific steps you have taken to address violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. 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 cannot complete addressing these violations within 48 hours, state the reason for the delay and the time within which you will do so. Your response should be sent by email to COVID-19-Task-Force-CDER@fda.hhs.gov (mailto:COVID-19-Task-Force-CDER@fda.hhs.gov)

Sincerely,
/S/

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

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1. The Phoenix Biotechnology, Inc. states “myoleander.com for sales phoenixbiotechnology.com for info” on its Twitter profile.
2. As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).
3. In addition, a press release issued by Avila Herbals, LLC states that Avila signed an exclusive global manufacturing and research and development agreement with Phoenix Biotechnology. Avila Herbals Announces Manufacturing and Research and Development Agreements with Phoenix Biotechnology. October 28, 2020 (Accessible at https://www.send2press.com/wire/avila-herbals-announces-manufacturing-and-research-and-development-agreements-with-phoenix-biotechnology/.)
4. 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 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.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx).
5. 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/).

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