



FDA U.S. FOOD & DRUG
ADMINISTRATION



CBER 20-06

WARNING LETTER

Date: August 27, 2020

TO: News@latticebiologics.com – Guy Cook
Chief Executive Officer
Lattice Biologics, Ltd.
512 E Madison Avenue, Suite 101
Belgrade, MT 59714

RE: Unapproved and Misbranded Product 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) have reviewed your website at www.latticebiologics.com, most recently in August 2020. We also recently reviewed your social media websites at www.youtube.com/watch?v=jyH85f9K-fk and www.twitter.com/latticebio. The FDA has learned that you market or distribute an amniotic fluid product (sometimes referred to as AmnioBoost) in the United States to mitigate, prevent, treat, diagnose, or cure Severe Acute Respiratory Syndrome (SARS) or Acute Respiratory Distress Syndrome (ARDS) related to Coronavirus Disease 2019 (COVID-19)¹ in people.

Based on our review, this product is an unapproved new drug under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355. 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).

Your product is also a biological product under section 351 of the Public Health Service Act (PHS Act), 42 U.S.C. § 262. In order to lawfully market a drug that is also a biological product, a valid biologics license application (BLA) must be in effect under the PHS Act. 42 U.S.C. § 262(a). Such licenses are issued only after a demonstration that the product is safe, pure, and potent. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug application (IND) in effect as specified by FDA regulations. 21 U.S.C. § 355(i); 42 U.S.C. § 262(a)(3); 21 C.F.R. 601.21; 21 C.F.R. Part 312. Your amniotic fluid product is not the subject of an approved BLA nor is there an IND in effect for your product.

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 declared a

¹ As explained in a later 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, 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

national emergency in response to COVID-19.³ Therefore, FDA is taking urgent measures to protect consumers from certain products that, without licensure, approval, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you market a product that is intended to mitigate, prevent, treat, diagnose, or cure SARS or ARDS related to COVID-19 in people. We request that you take immediate action to cease marketing such unlicensed, unapproved, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of SARS or ARDS related to COVID-19.

Some examples of the claims on your website and social media websites that establish the intended use of your product include the following. Additionally, the second example misleadingly represents it as safe and effective for the treatment or prevention of COVID-19.

- A YouTube video, titled “Stem Cells For COVID-19 . . . Lattice Biologics CEO injects himself with 1 million stem cells to test safety and efficacy,” through which you market your amniotic fluid product.” [from an April 2, 2020 YouTube video on your social media website www.youtube.com/watch?v=jyH85f9K-fk]
- The YouTube video marketing your amniotic fluid product, in which you state that you “hop[e] that the stem cells can go in and repair [severe lung damage] . . . even if you are at the hospital . . . you have this lung damage this is a reasonable treatment to try and repair that . . .” [from an April 2, 2020 YouTube video on your social media website www.youtube.com/watch?v=jyH85f9K-fk]
- Your representations that you are currently recruiting patients with “a laboratory confirmed infection with COVID-19 and evidence of lung involvement requiring supplemental oxygen or mechanical ventilation” to be administered “~ 5 million [stem cells] on the first day of enrollment and will receive another ~ 5 million stem cells on the second day of enrollment.” [from your website www.latticebiologics.com/amnioboost-for-covid-19-clinical-study-recruitment/]
- “NOW RECRUITING: Covid19 Patients for Free Clinical Trial. Lattice Biologics has begun enrolling patients in its Phase 1 clinical trial to address safety and efficacy of its novel stem cell technology.” [from a March 20, 2020 tweet on your social media website www.twitter.com/latticebio]
- “The Company . . . has decided to conduct the trial in Butte, Montana, and larger metropolitan areas as patients become available. The trial will not be conducted in hospitals, but rather in respiratory therapist offices . . . To date, the Company continues to enroll patients in Montana and is in negotiations with contract research organizations (CROs) to facilitate patient recruitment. Additional studies are expected to take place outside the U.S.; however, there are multiple companies and competitive trials underway for COVID-19, and patient recruitment is expected to be a significant hurdle to timeliness of studies.” [from your May 11, 2020 “Lattice Biologics Update” found at <https://www.businesswire.com/news/home/20200511005301/en/Lattice-Biologics-Update>]

You should take immediate action to correct any violations of the FD&C Act, the PHS Act, and FDA’s implementing regulations. This letter is not meant to be an all-inclusive list of violations that exist in connection with your product or operations.⁴ It is your responsibility to ensure that you and your products fully comply with the law.

declaration was renewed for another 90 days twice. The most recent renewal went into effect on July 25, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. July 23, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx>).

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/>).

⁴ For example, you also market your amniotic fluid product for intravenous administration to treat such diseases or

We advise you to review your website, social media websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your product as safe and effective for a COVID-19-related use for which it has not been licensed by FDA and that you do not make claims that misbrand the product in violation of the FD&C Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CBER@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 licensed, 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 marketing or distribution of COVID-19 related products in violation of the FD&C Act.⁵ 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 marketing of your unlicensed, 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(s) referenced above to be unapproved and misbranded products that cannot be legally marketed to consumers in the United States.

Please direct any inquiries to FDA at COVID-19-Task-Force-CBER@fda.hhs.gov.

conditions as Parkinson's disease, multiple sclerosis, and rheumatoid arthritis.

www.youtube.com/watch?v=jyH85f9K-fk. Although these claims are not the focus of this letter, please be advised that you must have an approved BLA to lawfully market your amniotic fluid product for such indications, or you must have an IND in effect to distribute your product for such clinical uses.

⁵ We note this Warning Letter also concerns the marketing of a COVID-19 related product in violation of the PHS Act.

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,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

Sincerely,

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