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]

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.

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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-declarion

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

Mary A. Malarkey
-S

Digitally signed by Mary A. Malarkey -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300054, cn=Mary A. Malarkey -S
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