WARNING LETTER

North Coast Biologics

MARCS-CMS 607532 — MAY 21, 2020

Product:

Biologics
Drugs

Recipient:

Johnny T. Stine
North Coast Biologics
4025 Stone Way N
Seattle, WA 98103
United States

Johnny@northcoastbio.com (mailto:Johnny@northcoastbio.com)

Issuing Office:

Center for Biologics Evaluation and Research (CBER)
United States

Federal Trade Commission (Federal Trade Commission)

WARNING LETTER

Date: May 21, 2020

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) have reviewed your website at www.northcoastbio.com and your social media websites at www.facebook.com/NCBio, www.facebook.com/jtstine, and www.linkedin.com/in/johnny-stine-58b032b on several dates throughout March and April 2020. You have used these websites to direct consumers to contact you to purchase your "nCoV19 spike protein vaccine." The FDA has observed that you have offered this COVID-19 vaccine product for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure 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), and misbranding your product while it is held for sale after shipment of the drug or one or more of its components in interstate commerce is prohibited under section 301(k) of the FD&C Act, 21 U.S.C. § 331(k).

Your product is also an unlicensed 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 (IND) application in effect as specified by FDA regulations. 21 U.S.C. § 355(i); 42 U.S.C. § 262(a)(3); 21 C.F.R. Part 312. Your 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 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 have offered a product for sale that is 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 unlicensed, unapproved, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your social media websites that establish the intended use of your product and misleadingly represent it as safe and/or effective for the prevention of COVID-19 include:

You, Johnny T Stine, commented on an April 17, 2020 post on Farhad Ghatan’s Facebook page (available online as of May 21, 2020):

- “Should I pop up and get your vaccine started????? . . . I can test you Farhad – if you’re able to get one of those sterile lances, I just need a few drops of blood. Don’t worry – I’m immune – I have boosted myself five times with my vaccine and I have a screaming antibody titer to the spike protein and the spike protein receptor binding domain . . . and I’m not mass producing it – I can’t produce enough for the masses, but in 18 months, when the virus is long gone, everyone will have access to the vaccine that I have now since everyone (70 players) are at the door steps of the FDA to get their product mass produced and injected into ‘you’ well after the threat . . . I’m VACCINATING people with the nCov19 spike protein – it’s a recombinantly expressed protein and it goes subQ by a tiny needle and the recipient begins making antibodies to the spike protein which is also saying that they will be protected from infection. It’s like any other recombinant protein vaccine. Not rocket science . . . I can test him for antibodies too, but my thinking is (if he hasn’t already been exposed/infected) just take the vaccine because it’s a lot quicker than bleeding someone and doing the antibody test.” [www.facebook.com/farhad.ghatan]

On March 21, 2020, your Johnny T Stine Facebook page posted:

- "Just vaccinated 12 people in west Seattle tonight . . . 12 more to vaccinate in Burien . . . off to Anchorage and PHX next." [www.facebook.com/jtstine]

On March 12, 2020, your North Coast Biologics Facebook page posted:

- "NCB's COVID19 spike protein vaccine is being made available to those who are either at risk or for anyone who simply needs some reassurance. Two shots get you a titer that binds the spike protein and the receptor binding domain. Message us here to create a spot in the queue. This isn't large scale industrial by any means …but locally, very effective." [www.facebook.com/NCBio]

On March 12, 2020, your Johnny T Stine Facebook page posted:

- "[M]y first question was 'Does it also use the ACE2 receptor to enter cells?' With the answer being yes, the vaccine design was the simplest I've ever done. Anti-sera to this peplomer (Spike protein) neutralize nCoV-19 and SARS in both animal models and also humans (Takeda) – so just a little plug for a targeted immune response to the receptor binding domain of nCov-19." [www.facebook.com/jtstine]

On March 6, 2020, your Johnny T Stine Facebook page posted:

- "Snap Shot of My Immune Response to COVID19 Vaccine: Per 2 million PBMC's (peripheral blood mononuclear cells), I have ~50 different target-specific IgG's to COVID19 vaccine that I made. This is not even after one boost – just one dose of vaccine." [www.facebook.com/jtstine]

As of March 4, 2020, your LinkedIn page stated:

- "I have made my nCoV-19 vaccine available. Not here to save the world or even small towns, but I'm providing this for those who may be at a greater risk or simply for personal comfort/assurances . . . the design of the vaccine was very straight forward and resulting spike protein/rbd vaccine robust. I'm titer-positive with neutralizing antibodies in particular but not limited to the RBD. I made the first batch for friends and family and due to the recent emergence here in WA-state, making the second batch now to assist those here in WA-state and surrounding areas. Private-message me here for assistance. I'll administer the vaccine right here in the Seattle area or come to your 'hood as I'm on the road a lot these days." [www.linkedin.com/in/johnny-stine-58b032b]
- [LinkedIn user inquired if you offer unlicensed and untested vaccines.] You replied: "Unlicensed???? Who would I be licensing it from if I'm the one who made it? Untested??? What part of "I'm titer-positive" do you not understand? Uncontrolled??? It either elicits an IgG response or it doesn't – and guess what – it did! My sera also blocked functional infection assays. Thus I'm immune. . . ." [www.linkedin.com/in/johnny-stine-58b032b]

On March 2, 2020, your Johnny T Stine Facebook page posted:

- "I made a vaccine to nCoV-'19 to the Spike protein and the receptor binding domain of this protein…After one shot (~25 ugs) and two weeks I was titer-positive to the vaccine. I contain blocking antibodies to the Spike protein RBD (receptor binding domain) which indicates these would be neutralized in vitro. After the primary immunization (without boosts) …guess what – my sera contains antibodies that are functionally inhibitory . . . I'm immune to nCoV-2019 . . . I'm offering my vaccine to people who simply feel that they need it because of increased risk or simply because it would make them comfortable . . . I'm not able to save the world much less a small town, but I can begin by taking orders for vaccinations. I can begin with 100 people because I'm limited on how much protein I can generate (the costly part). If

> interested parties pay $400/person, I can order up enough protein to be made to give each person a primary vaccination with two boosts (this is like the HepB vaccination protocol) . . . I will administer the vaccine here in the Seattle area or I'll come to you." [www.facebook.com/jtstine]

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. It is your responsibility to ensure that you and your products fully comply with the law.

We recognize that on April 28, 2020, you updated the North Coast Biologics Facebook page post from March 12, 2020, to say: "NCB's nCoV19 spike protein vaccine is no longer available due to a 'cease and desist' letter from the AG…" Yet certain of your claims described above that establish the intended use of your product and misleadingly represent it as safe and/or effective for the prevention of COVID-19 are still available online. Due to the serious public health concerns related to the marketing and sale of unapproved drugs for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, it is essential that you do not resume selling your product for prevention of COVID-19.

We advise you to review your 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** (mailto: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 sale or distribution of COVID-19 related products in violation of the FD&C Act.[4] This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products (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 unlicensed, unapproved, and unauthorized products 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 sold to consumers in the United States.

Please direct any inquiries to FDA at **COVID-19-Task-Force-CBER@fda.hhs.gov** (mailto:COVID-19-Task-Force-CBER@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 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** (mailto: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,

/S/

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

Sincerely,

/S/

Richard A. Quaresima
Acting Associate Director
Division of Advertising Practices

Federal Trade Commission

---

[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 (https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx)). The declaration was renewed for another 90 days on April 21, 2020. Secretary of Health and Human Services Alex M. Azar II,

Renewal of Determination that a Public Health Emergency Exists. April 21, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx (https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.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/ (https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/)).

[4] We note this Warning Letter also concerns the offer for sale of a COVID-19 related product in violation of the PHS Act.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)