



WARNING LETTER

Date: May 21, 2020

TO: Johnny@northcoastbio.com – Johnny T. Stine, North Coast Biologics, LLC

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** describing the specific steps you have taken to correct these violations.

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