WARNING LETTER

Date: September 9, 2020

TO: compounders@comcast.net – Redwards8423@gmail.com

Ron Edwards
Pharmacy Plus, Inc. dba Vital Care Compounder, LLC
115 South 40th Avenue
Hattiesburg, MS 39402-6600

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) reviewed your websites at the Internet address www.vitalcarecompounder.com and h10.6 (r)6 (c)-

- “This supplement pack contains a 14 day supply of four physician recommended supplements for prophylaxis, treatment and recovery from the Covid-19 virus.” [from your website at https://vitalcarecompounders.ecwid.com]

x Your product name, “COVID ‘POSITIVE’ PACK.”

x On the product page for “COVID ‘POSITIVE’ PACK” you include the following statement:
  - “This kit contains the standard covid kit comprised of Vitamin D3, Vitamin C, Zinc and Melatonin but also includes a 14 day supply of Nattokinase 100mg . . . routinely prescribed for covid positive patients. Ideal to keep in the home for emergency use when a family member tests positive for the virus.”

You should take immediate action to correct the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDER@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 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.