

To: Hays County Commissioners Court

From: Dr. Donna Campbell, Texas Senator

Date: April 6, 2020

Subject: Guangzhou WondFo Biotech Co., Ltd. SARS-CoV-2 Antibody Test

Dear Honorable Members,

I appreciate the Court's zeal to protect Hays County from CoVID-19. Realizing that most of us have never experience a time such as this, I urge you to proceed with the utmost caution in your decisions related to the virus. Please see the attached statement from the FDA regarding unauthorized fraudulent CoVID-19 test kits. The FDA states that they, "...want to alert the American public that, at this time the FDA has not authorized any test that is available to purchase for testing yourself at home for CoVID-19." The FDA is concerned about these "fraudulent health claims, tests, and products can pose serious health risks." Please read the attached FDA Alert. The best intentions can lead to unfortunate unintended consequences. Let's walk with caution, pray the virus is eradicated and Texans remain safe.

Respectfully

Donna Campbell MD

Texas Senator

FDA STATEMENT

Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits

For Immediate Release:

March 20, 2020

Statement From:

Commissioner of Food and Drugs - Food and Drug Administration Stephen M. Hahn M.D.

Associate Commissioner for Regulatory Affairs - Office of Regulatory Affairs Judith A. McMeekin Pharm.D.

Español

The U.S. Food and Drug Administration is actively and aggressively monitoring the market for any firms marketing products with fraudulent coronavirus (COVID-19) diagnostic, prevention and treatment claims as part of our ongoing efforts to protect public health during this pandemic. As a result of these activities, the agency is beginning to see unauthorized fraudulent test kits that are being marketed to test for COVID-19 in the home.

We want to alert the American public that, at this time, the FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. The FDA sees the public health value in expanding the availability of COVID-19 testing through safe and accurate tests that may include home collection, and we are actively working with test developers in this space.

Fraudulent health claims, tests, and products can pose serious health risks. They may keep some patients from seeking care or delay necessary medical treatment. The FDA reminds consumers to follow the U.S. Centers for Disease Control and Prevention's guidelines and speak to your medical provider if you have symptoms of COVID-19. Your medical provider will advise you about whether you should get tested and the process for being tested with an appropriate test.

The FDA will take appropriate action to protect consumers from bad actors who take advantage of a crisis to deceive the public by marketing tests that pose risks to patient health. This may include issuing warning letters, seizures or injunctions. We have already identified and issued warning letters to companies found selling and promoting fraudulent items, and we expect additional such actions will be forthcoming. Additionally, we are stepping up enforcement at ports of entry, including International Mail Facilities, to ensure these fraudulent products that originate outside the country do not enter through our borders.

If you are aware of fraudulent test kits for COVID-19, please report them to the FDA. We will continue to aggressively pursue those who place the public health at risk and hold bad actors accountable.

As a reminder, the President's Coronavirus Guidelines for America details simple actions we can take as individuals and families to #SlowTheSpread of coronavirus.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media:

Jeremy Kahn 301-796-8671

Consumer:

888-INFO-FDA