



**PRESS STATEMENT**

**FDA WARNS THE PUBLIC ON DRUGS AND VACCINES WITH  
UNPROVEN CLAIMS FOR COVID-19 TREATMENT**

**April 8, 2020**

The Food and Drug Administration (FDA) warns the public regarding the use of drugs or vaccines with unproven claims to be safe and effective in the treatment of COVID-19. Currently there are no registered drugs or vaccines that are licensed specifically for use in COVID-19 treatment or prevention.

There are on-going clinical trials to investigate the safety and efficacy of new and existing drugs, such as anti-viral, anti-bacterial, and anti-malarial agents in the treatment of COVID-19 patients. The World Health Organization (WHO) recently launched the Solidarity Trial, a large-scale clinical trial participated by many countries (including the Philippines), which aims to identify evidenced-based treatment regimen for COVID-19.

Manufacturers and vendors of unlicensed products such as PRODEX B and the Fabunan Antiviral Injections have been informed regarding the process and requirements to register their products with the FDA Center for Drug Regulation and Research (CDRR). No applications for product registration have been filed to date. Until such products are proven safe and effective for use in the treatment of COVID-19 they cannot be dispensed to the public nor can therapeutic claims be made.

The Food and Drug Administration maintains its mandate in ensuring the safety and efficacy of products to protect public health and commits to cooperate with all agencies to ensure prompt response to this global health crisis.

