

June 15, 2020

COM-2020-050

Dear provider of healthcare-related services,

As part of our effort to support you and keep you informed regarding rapidly changing measures taken in response to 2019 coronavirus disease (COVID-19), we want to notify you that the Food and Drug Administration (FDA) has revoked the emergency use authorization (EUA) issued on March 28, 2020 allowing for chloroquine phosphate (CQ) and hydroxychloroquine sulfate (HCQ) donated to the Strategic National Stockpile (SNS) to be used to treat certain hospitalized patients with COVID-19 when a clinical trial was not available or feasible.

The FDA determined that the legal criteria for the EUA are no longer met based on reviews of new data and published literature showing that CQ and HCQ are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. In addition, given the ongoing serious cardiac adverse events and other potential serious side effects, the known and potential benefits of CQ and HCQ no longer outweigh the known and potential risks for the authorized use.

We exhort you to read the full <u>Revocation of the EUA Letter</u> and the <u>FAQs on the Revocation of the EUA</u> for Hydroxychloroquine Sulfate and Chloroquine Phosphate for additional information.

The situation with the COVID-19 pandemic is dynamic and constantly changing. We strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO), to assure that your practices are consistent with the most actualized information.

PharmPix is committed to the health and wellness of our members. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137.

Regards,

Clinical Department

References:

 Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine. U.S. Food and Drug Administration. (2020). Retrieved June 2020, from https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and.

 FDA cautions use of hydroxychloroquine/chloroquine for COVID-19. U.S. Food and Drug Administration. (2020). Retrieved June 2020, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine-covid-19-outside-hydroxychloroquine-or-chloroquine