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## DIVISION of DRUG INFORMATION

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### **FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems**

The FDA is aware of reports of serious heart rhythm problems in patients with COVID-19 treated with hydroxychloroquine or chloroquine, often in combination with azithromycin and other QT prolonging medicines. We are also aware of increased use of these medicines through outpatient prescriptions. Therefore, we would like to remind health care professionals and patients of the known risks associated with both hydroxychloroquine and chloroquine. We will continue to investigate risks associated with the use of hydroxychloroquine and chloroquine for COVID-19 and communicate publicly when we have more information.

Hydroxychloroquine and chloroquine have not been shown to be safe and effective for treating or preventing COVID-19. They are being studied in clinical trials for COVID-19, and we authorized their temporary use during the COVID-19 pandemic for treatment of the virus in hospitalized patients when clinical trials are not available, or participation is not feasible, through an [Emergency Use Authorization \(EUA\)](#). The medicines being used under the [hydroxychloroquine/chloroquine EUA](#) are supplied from the Strategic National Stockpile, the national repository of critical medical supplies to be used during public health emergencies. This safety communication reminds physicians and the public of risk information set out in the [hydroxychloroquine](#) and [chloroquine healthcare provider fact sheets](#) that were required by the EUA.

Hydroxychloroquine and chloroquine can cause abnormal heart rhythms such as QT interval prolongation and a dangerously rapid heart rate called ventricular tachycardia. These risks may increase when these medicines are combined with other medicines known to prolong the QT interval, including the antibiotic azithromycin, which is also being used in some COVID-19 patients without FDA approval for this condition. Patients who also have other health issues such as heart and kidney disease are likely to be at increased risk of these heart problems when receiving these medicines.