

## **EXHIBIT 8**

[Preparedness](#)[Emergency](#)[About ASPR](#)

[PHE Home](#) > [Emergency](#) > [Events](#) > [2019 Novel Coronavirus](#) > [ASPR's Portfolio of COVID-19 Medical Countermeasures under Investigation](#) > [Chloroquine and hydroxychloroquine](#)

# Chloroquine and hydroxychloroquine

## ASPR's Portfolio of Investigational Medical Countermeasures being used to treat COVID-19

On June 15, 2020, the U.S. Food and Drug Administration (FDA) announced it had [revoked the Emergency Use Authorization \(EUA\)](#) for hydroxychloroquine sulfate and chloroquine phosphate based on new information. The EUA had initially permitted the use of chloroquine phosphate and hydroxychloroquine sulfate donated to HHS/ASPR's Strategic National Stockpile (SNS) for the treatment of certain hospitalized adults and adolescent COVID-19 patients when a clinical trial was unavailable, or participation in a clinical trial was not feasible.

Now, hydroxychloroquine sulfate and chloroquine phosphate can only be used for the treatment of COVID-19 as part of an ongoing clinical trial. Following the FDA's decision, the SNS will not release hydroxychloroquine sulfate or chloroquine phosphate to the states for use in hospitalized patients.

Recent results from a large randomized clinical trial in hospitalized patients, a population similar to the population for which chloroquine and hydroxychloroquine were authorized for emergency use, demonstrated that hydroxychloroquine showed no benefit in preventing mortality or speeding recovery. FDA has determined that the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use.

The decision to revoke this EUA was made [in consultation with the HHS/ASPR's Biomedical Advanced Research and Development Authority \(BARDA\)](#), which requested that FDA revoke the EUA. Like BARDA's earlier request to FDA to issue the EUA, BARDA's request to revoke the EUA is part of a collaborative, effort by the federal government to respond rapidly to this continuously evolving public health emergency. BARDA is no longer supporting clinical trials studying hydroxychloroquine sulfate or chloroquine phosphate for the treatment and prevention of COVID-19.

The revocation of the EUA does not change the existing FDA approvals of these drugs for other conditions. Some versions of chloroquine phosphate are approved for the treatment of malaria, and hydroxychloroquine sulfate is approved for the treatment of malaria, lupus, and rheumatoid arthritis.

[Letter Revoking Emergency Use Authorization](#)

[Letter of Authorization](#)

[Frequently Asked Questions](#)

### COVID-19: Coronavirus Disease 2019

[BARDA's Novel Coronavirus](#)

[Medical Countermeasure](#)

[Portfolio](#)

[ASPR's Portfolio of COVID-19](#)

[Medical Countermeasures](#)

[under Investigation](#)

[Working with BARDA on](#)

[COVID-19 Medical](#)

[Countermeasures](#)

[Strategic National Stockpile](#)

[Healthcare Provider](#)

[Resources from ASPR](#)

[TRACIE](#)

[HPP and Health Care System](#)

[Preparedness and Response](#)

[Emergency Declarations and](#)

[Waivers](#)

[Mental and Behavioral Health](#)

[Volunteering and Community](#)

[Service](#)

[Federal Nutrition Programs for](#)

[At-Risk Individuals](#)

[Online Training Webinars and](#)

[Peer-to-Peer Sessions](#)

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[Home](#) | [Contact Us](#) | [Accessibility](#) | [Privacy Policies](#) | [Disclaimer](#) | [HHS Viewers & Players](#) | [HHS Plain Language](#)

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