



June 24, 2020

Revocation of EUA for Hydroxychloroquine Sulfate and Chloroquine Phosphate for COVID-19 Treatment

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 these two products, which were donated to the 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.

Following the FDA's decision, the SNS will not release hydroxychloroquine sulfate or chloroquine phosphate to the states for use in hospitalized patients with COVID-19. To date, only hydroxychloroquine sulfate has been deployed from the SNS for the COVID-19 response.

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.

What Options are Available for Existing Product Received from the SNS?

In the absence of the EUA, public health authorities or wholesale distributors have the following options for the hydroxychloroquine sulfate they received from the SNS:

- They can continue to distribute the product in interstate commerce for the approved uses. The PREP Act declaration for COVID-19 countermeasures covers countermeasures used to mitigate the harm COVID-19 might cause, including shortages of the product for the approved use. The PREP Act declaration covers products deployed from the SNS until used.
 - Any product provided by the SNS cannot be charged to the patient; drug administration fees or prescription fees may be applied.
- Holders of the product may choose to destroy the product.

HHS is currently in contact with the companies that donated the products to the U.S. government to determine available options for those quantities remaining in the SNS as well as whether returns would be accepted from distributors or public health authorities. Additional information will be shared when it becomes available.

For more information, please see the FDA's [Frequently Asked Questions](#) document. Questions related to product deployed from the SNS may be submitted to the SNS Operations Center at sns.ops@cdc.gov.