

# The FDA Revokes Emergency Use Authorization for Hydroxychloroquine, Citing New Evidence



George Frey—AFP/Getty Images

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**T**he U.S. Food and Drug Administration (FDA) announced today that it is revoking the emergency use authorization for **hydroxychloroquine** and **chloroquine**, citing a lack of evidence that these drugs are effective for COVID-19.

Early on in the pandemic, doctors scrambling to find a way to treat the disease **widely prescribed** hydroxychloroquine to their sickest patients, based on thin evidence from a **handful** of relatively weak studies. However, recent research has made it increasingly clear that the drug is **likely ineffective** against the disease, and that it carries a risk of significant side effects, including heart problems.

The chief scientist for the FDA, Denise M. Hinton, announced the decision **in a letter** to the Biomedical Advanced Research and Development Authority (BARDA) on Monday. “Today’s request to revoke is based on new information, including **clinical trial** data results, that have led BARDA to conclude that this drug may not be effective to treat COVID-19,” she wrote, adding that it is “no longer reasonable” to believe that the drug combination’s benefits outweigh the potential side effects.

Hydroxychloroquine is a slightly different version of chloroquine, a drug discovered to fight **malaria** decades ago. Scientists developed hydroxychloroquine as a replacement for malaria treatment, with fewer side effects; today, in the U.S. it’s mainly prescribed to treat the **inflammation** related to **autoimmune disorders** like **rheumatoid arthritis** and **lupus**.

As the U.S. pandemic **surged** in March, President Donald Trump **championed** hydroxychloroquine as a potential COVID-19 treatment, calling it a possible “**game-changer**.” Trump **encouraged others** to take the drug, and later claimed to have undergone a **two-week regimen** of hydroxychloroquine himself in an effort to **ward off** the disease. Medical experts **widely criticized** President Trump for promoting a potentially dangerous drug before its benefits were proven, and warned of the possible risks of the public **self-medicating**.

The FDA said in a **statement** on Monday that the FDA regularly reviews drugs under an emergency use authorization, and has reviewed new information, including a large clinical trial of **hospitalized** patients that showed that the drug didn’t appear to help people get better faster, or reduce the risk of **mortality**.

“While additional clinical trials continue to evaluate the potential benefit of these drugs in treating or preventing COVID-19, we determined the emergency use authorization was no longer appropriate. This action was taken following a **rigorous assessment** by scientists in our Center for Drug Evaluation and Research,” Dr. Patrizia Cavazzoni, the acting director of the FDA’s Center for Drug Evaluation, said in the statement.

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