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FDA revokes EUA for Chloroquine, Hydroxychloroquine

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The FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA



The U.S. Food and Drug Administration (FDA) revoked the emergency use authorization (EUA) that allowed for chloroquine phosphate and hydroxychloroquine sulfate donated to the Strategic National Stockpile to be used to treat certain hospitalized patients with COVID-19 when a clinical trial was unavailable, or participation in a clinical trial was not feasible.

The agency determined that the legal criteria for issuing an EUA are no longer met. Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA.

Additionally, in light of ongoing serious cardiac adverse events and other potential serious side effects, the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use.

This is the statutory standard for issuance of an EUA. The Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services originally requested the EUA covering chloroquine and hydroxychloroquine, and the FDA granted the EUA on March 28, 2020 based on the science and data available at the time. Today, in consultation with the FDA, BARDA sent a letter to the FDA requesting revocation of the EUA based on up to date science and data.

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 on mortality or in speeding recovery.

This outcome was consistent with other new data, including data showing that the suggested dosing regimens for chloroquine and hydroxychloroquine are unlikely to kill or inhibit the virus that causes COVID-19. The totality of scientific evidence currently available indicate a lack of benefit.