Alert - June 15, 2020: Based on FDA's continued review of the scientific evidence available for hydroxychloroquine sulfate (HCQ) and chloroquine phosphate (CQ) to treat COVID-19, FDA has determined that the statutory criteria for EUA as outlined in Section 564(c)(2) of the Food, Drug, and Cosmetic Act are no longer met. Specifically, FDA has determined that CQ and HCQ 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 serious side effects, the known and potential benefits of CQ and HCQ no longer outweigh the known and potential risks for the authorized use. This warrants revocation of the EUA for HCQ and CQ for the treatment of COVID-19

Frequently Asked Questions on the Emergency Use Authorization (EUA) for Chloroquine Phosphate and Hydroxychloroquine Sulfate for Certain Hospitalized COVID-19 Patients

Q. What is an Emergency Use Authorization?
In certain types of emergencies, the HHS Secretary may issue a determination and declaration under the Food Drug and Cosmetic Act that permits FDA to issue emergency use authorizations (EUAs) to facilitate access to medical countermeasures (drugs, biologics, vaccines, and devices) that can be used to diagnose, treat or prevent a serious disease or condition in a public health emergency.

Products authorized for use in this way may not be approved by FDA for any use, or they may be approved for other uses but not for the emergency use. FDA decides whether the use of the product is likely to more helpful than harmful for the emergency use; i.e., the agency determines that the known and potential benefits of the medical products for their intended uses outweigh their known and potential risks. This authorization is reserved for emergency situations and is NOT the same as FDA approval or licensure.

Q: What does this EUA allow?
This EUA allows chloroquine phosphate and hydroxychloroquine sulfate donated to the Strategic National Stockpile (SNS) and distributed to states to be used by licensed health care providers to treat adults and teens hospitalized with COVID-19 who weigh more than 50 kg (110 pounds). The drugs should be used when participation in a clinical trial is not possible and if the health care provider feels the potential benefit to the patient outweighs the potential risk. Information on product distribution from the SNS can be found on this HHS webpage.

Q: Are chloroquine phosphate or hydroxychloroquine sulfate approved by the FDA to treat COVID-19?
A: No. Hydroxychloroquine sulfate and some versions of chloroquine phosphate are FDA-approved to treat malaria. Hydroxychloroquine sulfate is also FDA-approved to treat lupus and rheumatoid arthritis.

Q: Are there data showing that chloroquine phosphate or hydroxychloroquine sulfate might benefit patients with COVID-19?
A: In the lab, these drugs have been shown to prevent the growth of the virus that causes COVID-19. There are a few reports of patients with COVID-19 who received these drugs and improved. Some are reports of groups of patients, all of whom received the drug. It is not known whether it was the drug

that led to the improvement or whether there were other factors involved. We do not know if the treated patients' condition would have improved without the drug. To know this, there would have to be a group of similar patients who did not receive the drug (control).

Because chloroquine phosphate and hydroxychloroquine may possibly help very sick patients, FDA is allowing these drugs to be provided to certain hospitalized patients under an EUA issued March 28, 2020. Under the EUA, health care providers and patients are provided with information about the risks of these drugs. However, more data from clinical trials are necessary for us to determine whether chloroquine phosphate or hydroxychloroquine sulfate are safe and effective in treating or preventing COVID-19.

Q: Are there clinical trials currently underway looking at these drugs for COVID-19?
Yes. Clinical trials are underway and additional ones are being planned to determine if these drugs can benefit patients with COVID-19 infection who are either at home or in the hospital. These trials are also examining whether the drugs can prevent COVID-19 among health care workers, first responders, or people who have been in close contact with someone who is infected with COVID-19.
The EUA includes fact sheets that provide important information for health care providers and patients about using chloroquine phosphate and hydroxychloroquine sulfate in treating adults and teens hospitalized with COVID-19.

Q: Are there side effects of chloroquine phosphate or hydroxychloroquine sulfate?
Yes. All drugs have risks and there may be additional risks when chloroquine phosphate or hydroxychloroquine sulfate are used for COVID-19. Risks associated with these drugs include serious heart rhythm problems; low blood sugar, particularly among people with diabetes; anemia and other blood problems; worsening of seizures and other neurology (brain) problems; and retina (layer of eye tissue) damage that can cause vision problems.

Chloroquine phosphate and hydroxychloroquine sulfate can also interact with other drugs and cause serious problems, so patients should tell their health care provider about all the medicines they are taking, including vitamins and herbal products. FDA encourages health care providers to consult drug interaction checker tools to adequately assess for drug interactions to reduce any potential risks to patients.

Patients should also tell their health care providers if they have drug allergies; a heart condition, including heart rhythm problems; kidney disease; liver disease or hepatitis; diabetes or problems with low blood sugar; blood problems such as G6PD deficiency; an eye problem involving the retina; or if they drink large amounts of alcohol.

Health care providers should carefully review the EUA Health Care Provider Fact Sheets for chloroquine phosphate and hydroxychloroquine sulfate. More information about the drugs, including pharmacokinetics and the safety profile, is available through the search feature on the National Institutes of Health's Daily Med website.

Q. Is there a requirement for providers to report side effects as part of the EUA?
As part of the EUA, FDA is requiring health care providers who prescribe these drugs to report all serious adverse events through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178. This requirement is outlined in the EUA's health care provider fact sheet.

Q: Are there additional reporting requirements related to the EUA that go beyond safety?
Yes, the Biomedical Advanced Research Development Authority (BARDA) is requiring that health care providers must report information, including outcome data, related to the use hydroxychloroquine and chloroquine obtained from the SNS through this link.

Q: Should patients take these drugs to prevent COVID-19 outside of a clinical trial?
As these are prescription drugs, they should only be taken under the directions of a licensed practitioner. The drugs provided under this EUA are for a certain population of hospitalized patients with COVID-19. Given the uncertainty regarding the potential benefits and risks for COVID-19, it is critical to first have evidence from clinical trials. Researchers are currently studying the use of these drugs to prevent infection and decrease COVID 19 severity, primarily among people who are at greater risk of becoming infected with COVID-19. This includes health care workers, first responders, and people who have been in close contact with someone with COVID-19.

Q: Is the chloroquine phosphate used to treat disease in aquarium fish the same as the chloroquine phosphate that FDA has issued an EUA for as a COVID-19 treatment for humans?
No. Products marketed for veterinary use, "for research only," or otherwise not for human consumption have not been evaluated for safety or effectiveness and **should never be used by humans**. FDA is aware that chloroquine phosphate is marketed to treat disease in aquarium fish, but these products have not been evaluated by FDA to determine if they are safe, effective, properly manufactured, and adequately labeled. The agency continues to work with online marketplaces to remove these items, and many have been removed based on these efforts. Patients should not take any form of chloroquine unless it has been prescribed by a licensed health care provider. Chloroquine products also should not be given to pets or livestock unless prescribed by a veterinarian.

Q: How can chloroquine phosphate or hydroxychloroquine sulfate be obtained for use under the EUA?
These products can be obtained from the SNS by state health officials, not by individual hospitals or pharmacies. To request these drugs for use under the EUA, state health officials can contact their Regional Emergency Coordinator. Certain hospitalized patients may be able to obtain these drugs through their health care providers when they cannot participate in a clinical trial.

Q: Who do I contact if I would like to obtain chloroquine phosphate or hydroxychloroquine sulfate for a clinical trial?
For investigators interested in conducting clinical trials with these drugs from the SNS Contact information is included below:

- Toll-free #: 1-877-366-1018, or +1 919 650 6197 for international dialing
- Email address: COVID19clinicaltrials@druginfo.com