EUA 077

EUA REQUEST RESPONSE

John E. McKinnon, MD, MSc
Senior Staff Infectious Diseases, Fellowship research coordinator
Department of Medicine
Henry Ford Hospital
Clara Ford Pavilion, Suite 322
2799 W. Grand Blvd.
Detroit, MI 48202

Dear Dr. McKinnon:

We have reviewed your July 6, 2020, request for FDA to issue an Emergency Use Authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3) to authorize hydroxychloroquine sulfate for emergency use for disease prevention (pre or post exposure prophylaxis) and treatment of early COVID-19 infections. Additionally, this response refers to your amendments that contained responses to our information requests dated July 23, 2020.

We have reviewed all of the relevant information available to us, including the studies that you have referenced, and we are declining to issue an EUA for hydroxychloroquine sulfate for disease prevention and treatment of early COVID-19 infections at this time. In this case, we have concluded that, based on the totality of the scientific information available, it is unlikely that hydroxychloroquine sulfate may be effective in disease prevention or treatment of early COVID-19 infections. Further, in light of ongoing reports of serious cardiac adverse events and other adverse drug effects, we conclude that the known and potential benefits of hydroxychloroquine sulfate in disease prevention or treatment of early COVID-19 infections do not outweigh the known and potential risks for these proposed uses.

While we are declining to issue an EUA at this time, we agree that there is a need for effective therapeutics for the prevention of COVID-19 and the treatment of patients with early COVID-19 infections. We further agree that randomized controlled trials are needed to evaluate new therapeutics to address this unmet need. We note that a large randomized, controlled trial of hydroxychloroquine sulfate for the prevention of COVID-19 in health care workers remains open to enrollment in the U.S.[1]

We also note that, in addition to your request for emergency use authorization of hydroxychloroquine sulfate, you have made certain requests relating to a healthcare provider's ability to prescribe medications as part of a physician-patient relationship and

[1] *See:* https://heroesresearch.org/hero-hcq/ ; We also note that researchers at Henry Ford Hospital are conducting a trial using HCQ for prevention of COVID-19.

the requirements associated with Investigational New Drug (IND) applications for hydroxychloroquine sulfate. We do not believe that these requests are pertinent to the evaluation of your request for an emergency use authorization; therefore, we are not addressing them as part of this response.

FDA remains committed to fostering the development and availability of potential treatments for COVID-19. Despite FDA declining to issue an EUA for hydroxychloroquine sulfate at this time, FDA remains committed to working with you and other interested parties in the development of products to prevent or treat COVID-19. If and when additional data become available, such as data from randomized controlled trials, that you believe is adequate to enable FDA to conclude that the known and potential benefits outweigh the known and potential risks of this product, you can submit a new EUA request to FDA at that time. We will review any such submission promptly.

Forward all future EUA-related communications, in triplicate, identified by the above pre-EUA number, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antivirals
5901-B Ammendale Road
Beltsville, MD 20705-1266

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If you have any questions, contact Alicia Moruf, Regulatory Project Manager, at 301-796-3952.

Sincerely,

{See appended electronic signature page}

Peter Stein, MD
Director, Office of New Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALICIA MORUF
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