April 23, 2020

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061, HFA-305
Rockville, MD 20852

Dear Persons:

RE: Revoke the EUA for hydroxychloroquine

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act and any applicable Prescription Drug Amendments; the Code of Federal Regulations, Title 21, Parts 312 & 314; the FDA's January 2017 Guidance* on Emergency Use Authorization, EUA, of Medical Products and/or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs:

Revoke/withdraw the EUA for hydroxychloroquine and any identical, similar, or related drug products.**

This is the ACTION REQUESTED in this petition.

The STATEMENT OF GROUNDS for requesting the aforementioned action are as follows:

The hydroxychloroquine EUA fails to meet the following Guidance criteria:*

At III. B. 1. b., [page 7 of the Guidance], Evidence of Effectiveness:

Reports from the VA Study and Sweden demonstrate not only a lack of effectiveness, but COVID-19 patients, treated with hydroxychloroquine, do not show comparable survival and have experienced adverse effects.

At III. B. 1. c., [page 8 of the Guidance], Risk-Benefit:

Cardiac effects are a major risk; that is, "cardiac failure and in some cases fatal outcomes...hydroxychloroquine prolongs the QT interval; ventricular arrhythmias and torsade de pointes have been reported." Quotations are extracted directly from the hydroxychloroquine's labeling on dailymed. Without a benefit to off-set these major risks, hydroxychloroquine fails to meet this EUA criterion.

** As defined in 21 CFR 310.6 (b) (1)

At III. B. 1. d., [page 8 of the Guidance], No Alternatives:

A search of clinicaltrials.gov, as of April 23, 2020, reveals thirty six, 36, drug categories for interventions against COVID-19. Thus, there are many alternatives to hydroxychloroquine.

Conclusion: Hydroxychloroquine fails to meet three [3] out of the four [4] EUA criteria in FDA Guidance document. Revocation of the EUA is the next prudent step to protect the American public.

ENVIRONMENTAL IMPACT: A categorical exclusion is requested under 21 CFR 25.34 for this petition.

CERTIFICATION: The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information*** and views*** on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

(b) (6) [redacted]

(Dr.) S. Albert Edwards, PharmD, RAC, FRAPS

(b) (6) [redacted]

***FDA has access to a vast array of information sources beyond the published literature, especially via reported and analyzed adverse event data and memoranda of understanding with several safety-conscious countries; it is more likely than not that FDA can more effectively research all published and unpublished data bases than the private citizen for relevant scientific information on this hydroxychloroquine decision.

*** Views of those outside the science world are plentiful but should be excluded, as they are driven by anecdotal and unscientific media reports and speculation not designed to advance our rational understanding of COVID-19 drug therapy or the safety of the American public.