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U.S. DISTRICT COURT
N.D. OF ALABAMA

FDA U.S. FOOD & DRUG ADMINISTRATION

Simone Gold
America's Frontline Doctors c/o Free Speech Foundation
2934-1/2 Beverly Glen Circle #314
Los Angeles, CA 90077

Sent via email to: info@aflds.com

April, 8, 2021

Re: Docket No. FDA-2020-P-2066

Dear Ms. Gold:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 13, 2020. Your petition requests that the Agency exempt from prescription-dispensing requirements Plaquenil™ and equivalent hydroxychloroquine sulfate based drugs for use in COVID-19 prophylaxis, pursuant to 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b),.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2021.04.08 10:22:59 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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