Kip Vought, Vice President
Clinipace Worldwide / US Regional Office
4840 Pearl East Circle
Boulder, CO 80301

Docket No. FDA-2013-P-0170

Dear Kip Vought:

This is in response to your petition received on February 12, 2013, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Hydroxychloroquine Sulfate Tablets, 100 mg, 300 mg, and 400 mg. The listed drug product to which you refer in your petition is Plaquenil (hydroxychloroquine sulfate) Tablets, 200 mg, approved under NDA 009768 and held by Concordia Pharmaceuticals, Inc.

Your request involves a change in strength from that of the listed drug product (i.e., from 200 mg to 100 mg, 300 mg, and 400 mg). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act.

We have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93 and have determined that it is approved. This letter represents FDA's determination that an ANDA may be submitted for the above-referenced drug product.

Under section 505(j)(2)(C) of the Act and 21 CFR 314.93(e)(1), FDA will approve a petition properly submitted under § 314.93 seeking a strength that differs from the strength of the listed drug product unless it finds that one of the grounds for denying such a petition applies.

The Agency finds that the proposed change in strength for the proposed drug product does not pose questions of safety or effectiveness. The uses, doses, and route of administration of the proposed drug product are the same as that of the listed drug product. The proposed change is consistent with dosing recommendations in the labeling of the listed drug. In addition, if shown to meet bioequivalence requirements, the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug product. Therefore, FDA concludes that the proposed change would not jeopardize the safe or effective use of the product so as to necessitate significant labeling changes, and investigations are not necessary to show the safety and effectiveness of the proposed strength.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by FDA.

To permit review of your ANDA submission, you must submit all information required under section

505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioequivalence requirements under section 505(j)(2)(A)(iv) of the Act. During the review of your application, FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you must refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. 21 CFR 314.94(a)(3)(iii). Please note that once a new drug application is approved for a product that is the same as the subject of an approved petition, such petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

Trueman Sharp -S

Digitally signed by Trueman Sharp -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Trueman Sharp -S, 0.9.2342.19200300.100.1.1=2001369000
Date: 2018.11.26 12:15:30 -05'00'

for John Peters, M.D.
Deputy Director
Office of Generic Drugs
Center for Drug Evaluation and Research