DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 12, 2013

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

Dear Mr. Vought:

Your petition to the Food and Drug Administration requesting to declare that hydroxychloroquine sulfate tablets 100, 300, and 400 mg are suitable for submission in an Abbreviated New Drug Application (ANDA), was received by this office on 2/12/2013. It was assigned docket number FDA-2013-P-0170/CP1, and it was filed on 2/12/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)