



ANDA 090249/S-003 and S-004

**CHANGES BEING EFFECTED  
APPROVAL**

IQVIA RDS Inc.  
U.S. Agent for Ipca Laboratories Limited  
1801 Rockville Pike Suite 300  
Rockville, MD 20852  
Attention: Janelle Delk  
Director, Global Regulatory Affairs

Dear Madam:

This is in reference to your supplemental abbreviated new drug applications (sANDAs) received for review on March 19, 2018 (S-003) and January 18, 2019 (S-004), submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Chloroquine Phosphate Tablets USP, 500 mg.

The sANDAs, submitted as "Changes Being Effected," provide for:

- S-003: Revised labeling to be in accordance with the reference listed drug, Aralen® Tablets, NDA 006002/S-044, approved on July 13, 2017.
- S-004: Revised labeling to be in accordance with the reference listed drug, Aralen® Tablets, NDA 006002/S-045, approved on October 24, 2018.

We have completed the review of these sANDAs and they are approved.

**REPORTING REQUIREMENTS**

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506l of the FD&C Act. The Office of Generic Drugs should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506l(b) of the FD&C Act, you are required to notify the Office of Generic Drugs in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

**ANNUAL FACILITY FEES**

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions <sup>1</sup> with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

Sincerely yours,

*{See appended electronic signature page}*

For Rachel Goehe, Ph.D.  
Director  
Division of Labeling Review  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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<sup>1</sup> Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).



Keisha  
Redd

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