ANDA 090610/S-004 and S-005

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-004) and January 18, 2019 (S-005), submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Chloroquine Phosphate Tablets USP, 250 mg.

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

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

- S-005: 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 supplemental applications. They are approved, effective on the date of this letter. However, please make the following revisions to the labeling and submit it in your next Annual Report, provided the change is described in full.

PRESCRIBING INFORMATION

a. HOW SUPPLIED: Add the equivalency statement to be aligned with the RLD.

b. Manufacture statement: Add the text “Manufactured” to the by: statement.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I 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 506I(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 [1] 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

[1] 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

Digitally signed by Keisha Redd
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