



ANDA 040657/S-007

**CHANGES BEING EFFECTED  
APPROVAL**

Zydus Pharmaceuticals (USA) Inc.  
73-B Route 31 North  
Pennington, NJ 08534  
Attention: Srinivas Gurram  
Vice President and Head of RA and QA - North America

Dear Sir:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on February 16, 2017, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Hydroxychloroquine Sulfate Tablets USP, 200 mg.

The sANDA, submitted as "Changes Being Effected," provides for:

Revised insert labeling to be in accordance with the RLD, Plaquenil, NDA 009768/S-037, S-045, and S-047, approved on January 27, 2017.

We have completed the review of this supplemental application. It is approved, effective on the date of this letter. However, please make the following revisions to the labeling and submit them in your next Annual Report, provided the changes are described in full.

**1. CARTON LABELING**

Since this drug product is light sensitive, please add "Keep in carton until time of use", "Protect from light" and "This unit-dose package is not child-resistant".

**2. PRESCRIBING INFORMATION**

Revise the first paragraph of the DESCRIPTION section to be consistent with the RLD.

"Hydroxychloroquine sulfate is a white or practically white, crystalline powder, freely soluble in water; practically insoluble in alcohol, chloroform, and in ether. The chemical name for hydroxychloroquine sulfate is..."

## **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<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).



Ellen  
Koo

Digitally signed by Ellen Koo

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