ANDA 040104/S-025

CHANGES BEING EFFECTED
APPROVAL

Sandoz Inc.
100 College Road West
Princeton, NJ 08540
Attention: Gregory Seitz
Executive Director, Regulatory Affairs

Dear Mr. Seitz:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on July 10, 2017, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hydroxychloroquine Sulfate Tablets USP, 200 mg.

This "Changes Being Effected" supplemental abbreviated new drug application provides for revised labeling to be in accordance with the labeling for the reference listed drug (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. PRESCRIBING INFORMATION
    a. HOW SUPPLIED
        i. Revise the drug product description to be consistent with the finished drug product specifications approved on October 3, 2017 (ANDA 040104/S-026), e.g., delete (b) (4)
        ii. Add the following statement to be consistent with the RLD labeling: "Do not crush or divide hydroxychloroquine sulfate film-coated tablets (see DOSAGE AND ADMINISTRATION)."

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 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.

The material submitted is being retained in our files. If you have any questions, contact Annie Guan, Labeling Project Manager, at (301) 796-3526 or annie.guan@fda.hhs.gov.

Sincerely,

{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
U.S. Food and Drug Administration

Annie Guan

Digitally signed by Annie Guan
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