



ANDA 040516/S-012

**PRIOR APPROVAL SUPPLEMENT
APPROVAL**

Impax Laboratories, LLC
50 Horseblock Road
Brookhaven, NJ 11719
Attention: Pavan Kumar
Vice President, Global Regulatory Affairs

Dear Pavan Kumar:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on October 22, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Chloroquine Phosphate Tablets USP, 500 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as "Prior Approval Supplement," provides for:

- Addition of Amneal Pharmaceuticals Private Limited, located at 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka Bavla, Ahmedabad, Gujarat, 382220 India (FEI: 3008223599; DUNS: 915076126), as a Drug Product Manufacturing, Packaging and Labeling Site, In-Process Material Manufacturing site, Stability samples storage site, Storage site for API, Finished product & In-process material, Testing of API release, Finished product release, In-Process material release, and Finished product stability facility
- Addition of Natco Pharma Limited – Chemical Division, located at Mekaguda Village, Nandigama Mandal, Rengareddy District, Telangana 509223 India (FEI: 3004065860; DUNS: 862497174), as a site referenced under DMF 033067 for the manufacturing and packaging of Drug Substance, Intermediate Manufacturing and testing, Micronization, Release and Stability testing of drug substance, Stability sample storage site, One time testing of Elemental Impurity, Drug Substance Analytical method validation.

We have completed the review of this sANDA, as amended, and it is **approved**.

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 Agency 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 Agency 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.

If your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts we remind you that you must comply with the postmarketing safety reporting requirements for an approved combination product (21 CFR Part 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions¹ 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 1st 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 or active pharmaceutical ingredients 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.

If you have further questions regarding this supplement, you may contact Christopher LaFleur, Regulatory Business Process Manager, at (240) 402 - 4724.

Sincerely yours,

{See appended electronic signature page}

For:

Paul Schwartz, Ph.D.
Director, Division of Post Marketing Activities II
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
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).



Karen
Bernard

Digitally signed by Karen Bernard

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