



ANDA 074737/S-012

**CHANGES BEING EFFECTED IN 30 DAYS  
APPROVAL**

Grace Consulting Services Inc.  
U.S. Agent for Annora Pharma Private Limited  
121 New England Ave  
Piscataway, NJ 08854  
Attention: Soma Raju

Dear Soma Raju:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on May 7, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Captopril Tablets USP, 12.5 mg, 25 mg, 50 mg, 100 mg.

The sANDA, submitted as "Changes Being Effected in 30 Days," provides for:

- 1) An alternate drug product manufacturing and packaging site with corresponding process and equipment changes
- 2) Drug product specification revision to be in compliance with USP monograph
- 3) Alternate container closure system components

We have completed the review of this sANDA 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 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<sup>st</sup> 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 Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

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

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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).



Niles  
Ron

Digitally signed by Niles Ron

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