ANDA 216990

ANDA APPROVAL

Torrent Pharma Inc.
U.S. Agent for Torrent Pharmaceuticals Limited
106 Allen Road, Suite 305
Basking Ridge, NJ 07920
Attention: Saroja Gorantla
Associate Director

Dear Saroja Gorantla:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 14, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Tiopronin Delayed-Release Tablets, 100 mg and 300 mg.

Reference is also made to the complete response letter issued by this office on September 14, 2023, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly, the ANDA is **approved**, effective on the date of this letter. We have determined your Tiopronin Delayed-Release Tablets, 100 mg and 300 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Thiola EC Delayed-Release Tablets, 100 mg and 300 mg, of Mission Pharmacal Company (Mission).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated January 24, 2022.

The RLD upon which you have based your ANDA, Mission's Thiola EC Delayed-Release Tablets, 100 mg and 300 mg, is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
11,458,104 (the '104 patent)	November 14, 2038

With respect to the '104 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the FD&C Act that this is a method-of-use patent that does not claim any indication for which you are seeking approval under your ANDA.

We note that Torrent Pharmaceuticals Limited (Torrent) was granted a Competitive Generic Therapy (CGT) designation for Tiopronin Delayed-Release Tablets, 100 mg and 300 mg. However, your drug products not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in the Orange Book for the RLD at the time of submission of your ANDA.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

John
Ibrahim

Digitally signed by John Ibrahim
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