ANDA 040268/S-033

SUPPLEMENT APPROVAL

Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Drive
Salisbury, MD 21801
Attention: Scott Mcguinness
Sr. Manager, Regulatory Affairs

Dear Scott Mcguinness:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) received November 25, 2024, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prochlorperazine Maleate Tablets USP, 5 mg and 10 mg.

We also refer to our letter dated September 13, 2024, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Prochlorperazine Maleate Tablets, USP. This information pertains to the risk of hyperprolactinemia.

This sANDA provides for revisions to the labeling for Prochlorperazine Maleate Tablets, USP and the agreed upon changes to the language included in our electronic communication dated November 13, 2024.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

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,

{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
Date: 1/22/2025 09:56:54AM
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