NDA 214487/S-001

SUPPLEMENT APPROVAL

Chemocentryx, Inc.
Attention: Suhasini Kanagala, PhD
835 Industrial Road, Suite 600
San Carlos, CA 94070

Dear Dr. Kanagala:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 13, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TAVNEOS (avacopan) oral capsules.

The sNDA, submitted as " Changes Being Effected in 30 Days" and subsequently reviewed as “Changes Being Effected” supplemental new drug application provides for:

Updates to the container and carton labeling which include the following:

- Replacement of the symbol “TM” in the product title with the symbol “®”
- Addition of the statement “Pharmacist: Dispense with accompanying Medication Guide to each patient” and an associated update to the “Recommended Dosage” statement
- Inclusion of the product logo

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 214487/S-001.**” Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Megan Nguyen, Regulatory Business Process Manager, at Megan.Nguyen@fda.hhs.gov or (301) 796 - 7826.

Sincerely,

{See appended electronic signature page}

For:
Gurpreet Gill-Sangha, Ph.D.
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

Rohit Kolhatkar

Digitally signed by Rohit Kolhatkar
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