NDA 214869/S-003

SUPPLEMENT APPROVAL

Avion Pharmaceuticals, LLC
Attention: Noor Araim
Senior Manager, Regulatory Affairs
1880 Mcfarland Parkway
Suite 110
Alpahretta, GA 30005

Dear Ms. Araim:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 4, 2022, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dhivy (carbidopa and levodopa) Tablets.

This "Changes Being Effected" supplemental new drug application provides for the addition of information to the container label to better explain the optional fractionation of the functionally scored Dhivy tablet into four segments where each segment "contains 6.25 mg carbidopa (anhydrous equivalent) and 25 mg levodopa".

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. 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 214869/S-003.**" 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, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, Branch 3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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