DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 021485/S-038

SUPPLEMENT APPROVAL

B & H Consulting Services, Inc.
U.S. Agent for: Orion Corporation
Attention: Sandy Lee, RAC
Associate Director, CMC and Regulatory Affairs
50 Division Street Suite 206
Somerville, NJ 08876

Dear Ms. Lee:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 26, 2018, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for STALEVO® (Carbidopa, Levodopa, and Entacapone) Tablets.

This "Changes Being Effected" supplemental new drug application provides for a revision to the container trade labels for all strengths of STALEVO® Film-Coated Tablets to reflect a country of origin ruling from the U.S. Customs and Border Protection Agency.

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 text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton labels that are identical to the enclosed carton and immediate 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 titled Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3). For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 021485/S-038**." 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, PharmD, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Container Labeling

David Lewis

Digitally signed by David Lewis
Date: 9/21/2018 10:54:22AM
GUID: 508da72000029f287fa31e664741b577