DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20796/S-015
NDA 21485/S-020

SUPPLEMENT APPROVAL

Orion Corporation
Attention: Sandy Lee
Project Manager
B&H Consulting Services, Inc.
55 North Gaston Avenue
Somerville, NJ 08876

Dear Ms. Lee:

Please refer to your Supplemental New Drug Applications (sNDAs) dated February 17, 2009, received February 18, 2009 (supplement 15), and dated May 28, 2009, received May 29, 2009 (supplement 20) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Comtan® (entacapone) Tablets and Stalevo® (levodopa/carbidopa/entacapone) Tablets, respectively.

We acknowledge receipt of your additional submissions dated February 26, 2009, April 3, 2009 and May 14, 2009 for Comtan Tablets and March 30, 2010 for both Comtan and Stalevo supplements.

These ”Prior Approval” supplemental new drug applications proposed changes to the PRECAUTIONS section of the labeling regarding colitis.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate the submissions, “SPL for approved NDA 020796/S-015 or NDA 021485/S-020.”

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Stacy Metz, PharmD, at (301) 796-2139.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL G KATZ
10/11/2010