DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-485/S-008
NDA 21-485/S-012

Orion Corporation
Attention: Marguerite Coleman
Regulatory Affairs Consultant
B&H Consulting Services, Inc.
55 North Gaston Avenue
Somerville, NJ 08876

Dear Ms. Coleman:

Please refer to your supplemental new drug applications dated December 14, 2006, received December 19, 2006 (supplement 8), and dated May 24, 2007, and received May 30, 2007 (supplement 12) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Stalevo® (levodopa/carbidopa/entacapone) Tablets 200/50/200 mg.

Supplement 8 provides for the addition of information regarding intense urges to gamble, increased sexual urges, and other intense urges in patients using medications to treat Parkinson's disease. Supplement 12 provides for the addition of information regarding melanoma to the PRECAUTIONS section of the package insert.

We also refer to the approval letter dated February 2, 2009. We have noted that the labeling attached to the February 2, 2009 letter does not contain all of the approved changes. We will issue a replacement action letter with the currently approved label attached. Please note that the date of the action will be unchanged, but the signature time will be one minute later to permit differentiation between the two action letters.

If you have any questions, call me at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

Susan Daugherty
Senior Regulatory Health Project manager
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Susan B. Daugherty

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