DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-485

Orion Pharma, Inc.
Attention: Pamela Schaneen, Sr. Regulatory Affairs
25A Vreeland Road, Suite 100
Florham Park, NJ 07932

Dear Ms. Schaneen:

Please refer to your new drug application (NDA) dated June 24, 2002, received June 26, 2002, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Stalevo 50 (carbidopa/ levodopa/ entacapone 12.5/50/200), Stalevo 100 (carbidopa/levodopa/entacapone 25/100/200), and Stalevo 150 (carbidopa/levodopa/entacapone 37.5/150/200) Tablets

We acknowledge receipt of your submissions dated May 2, 2003, and May 23, 2003.

The May 2, 2003 submission constituted a complete response to our April 25, 2003 action letter.

This new drug application provides for the following indications in the treatment of patients with idiopathic Parkinson's disease:

1. To substitute (with equivalent strength of each of the three components) for immediate release carbidopa/levodopa and entacapone previously administered as individual products.
2. To replace immediate release carbidopa/levodopa therapy (without entacapone) when patients experience the signs and symptoms of end-of-dose "wearing-off" (only for patients taking a total daily dose of levodopa of 600mg or less and not experiencing dyskinesias).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the package insert submission dated May 23, 2003.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified

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 CDR Teresa Wheelous, Sr. Regulatory Project Manager, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation 1
Center of Drugs Evaluation and Research

Enclosure

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

/s/

Russell Katz

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