CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-485

APPROVAL LETTER

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-485

APPROVABLE LETTERS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-485

Orion Pharma
Attention: Ilkka Larma
Vice President, Drug Regulatory Affairs
25A Vreeland Road, Suite 100
Florham Park, NJ 07932

Dear Mr. Larma:

Please refer to your new drug application (NDA) dated June 24, 2003, received June 26, 2003, submitted under section 505(b) 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:

July 3, 2003	August 28, 2003	November 8, 2003
November 14, 2003	November 27, 2003	December 3, 2003
March 7, 2003	March 13, 2003	March 19, 2003
April 4, 2003	April 9, 2003	April 16, 2003
April 21, 2003	April 22, 2003	

We completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit draft labeling revised as provided in the following attachment.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the

application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

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

Attachment

32 Draft Labeling Page(s) Withheld

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
4/25/03 02:55:49 PM