

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**17-962/S-063**

**17-962/S-064**

**APPROVABLE LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 17-962/S-063 & S-064

Novartis Pharmaceuticals Corporation  
Attention: John R. Cutt, Ph.D.  
Director, Drug Regulatory Affairs  
One Health Plaza  
East Hanover, New Jersey 07936

Dear Dr. Cutt:

Please refer to your supplemental new drug applications dated April 15, 2002 (S-063) and May 9, 2003 (S-064), received April 19 and May 12, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Parlodel<sup>®</sup> (bromocriptine mesylate) Capsules and Tablets.

These supplemental new drug applications provide for the addition of a "Geriatric Use" subsection (S-063) and paragraphs regarding post marketing safety data relating to sudden onset of sleep and pleuropulmonary and pericardial changes during treatment in patients with Parkinson's disease (S-064).

We have completed our review of your supplemental applications, and they are approvable. Before these applications may be approved, however, you must submit draft labeling revised to include an additional paragraph concerning neuroleptic malignant syndrome (NMS) in the 'Parkinson's Disease' section.

Provide supporting documentation for the rates of dizziness, drowsiness, fainting and syncope for the 'Information for Patients' section.

In addition, all previous revisions as, reflected in the most recently approved package insert, must be included. To facilitate review of your submission, provide a highlighted or marked-up copy that shows the changes.

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

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, or 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.

If you have any questions, please call Archana Reddy, M.P.H., Regulatory Project Manager,  
at (301) 827-4260.

Sincerely,

*{See appended electronic signature page}*

Daniel Shames, M.D.

Director

Division of Reproductive and Urologic Drug Products

Office of Drug Evaluation III

Center for Drug Evaluation and Research

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/s/

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