CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

17-962/S-063

17-962/S-064

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

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

Novartis Pharmaceuticals Corporation
Attention: Gregory R. King
Senior TA Manager, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. King:

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

We acknowledge receipt of your submissions dated May 5, 2005 (2).

Your submissions of May 5, 2005 constituted a complete response to our January 15, 2004 action letter.

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

The final printed labeling (FPL) must be identical to the enclosed labeling that were submitted May 5, 2005, for the package insert.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 17-962/S-063, S-064.**" Approval of these submissions by FDA is not required before the labeling is used.

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 John Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 796-0932.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D., F.A.C.S.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Agreed-upon package insert

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

/s/

Daniel A. Shames
11/9/2005 06:29:53 PM