DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-187/S-066/S-067
NDA 18-029/S-037/S-038
NDA 21-284/S-006/S-008

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
Senior Associate Director
Drug Regulatory Affairs
One Health Plaza
East Hanover, New Jersey 07936-1080

Dear Ms. Stiles:

Please refer to your supplemental new drug applications dated November 21, 2005 (NDA 10-187/S-066 & 18-029/S-037), November 10, 2005 (21-284/S-006), March 23, 2006 (NDA 10-187/S-067 & 18-029/S-038), and March 17, 2006 (NDA 21-284/S-008), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ritalin (methylphenidate hydrochloride) Tablets (NDA 10-187), Ritalin SR (methylphenidate hydrochloride) Sustained-Release Tablets (NDA 18-029), and Ritalin LA (methylphenidate hydrochloride) Extended-Release Capsules (NDA 21-284).

Reference is also made to an Agency action letter on the above applications dated May 22, 2006.

We acknowledge receipt of your submissions dated June 28, 2006 (NDA 10-187/S066/S-067 & 18-029/S-037/S-038) and June 22, 2006 (NDA 21-284/S-006/S-008).

Your submissions of June 22, and 28, 2006, constituted a complete response to our May 22, 2006 letter.

These "Changes Being Effected" supplemental new drug applications provide for the following CNS stimulant class labeling revisions as requested in our May 22, 2006 letter:

- revisions to the Ritalin/Ritalin-SR Warnings and Precautions sections of the package insert.
- revisions to the Ritalin LA Warnings section of the package insert.

We note that you have also updated the patient package insert (PPI) for Ritalin LA so that it is in alignment with the class labeling revisions. Although this is acceptable, at this time, we intend to request a Medication Guide in the near future for all of the CNS stimulants. The Medication Guide will then replace the PPI.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Felicia Curtis, Regulatory Project Manager, at (301) 796-0877.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug 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/

Thomas Laughren
8/8/2006 09:06:01 AM