DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-187 / S-069
NDA 18-029 / S-040
NDA 21-284 / S-011

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
One Health Plaza
East Hanover, NJ 07936

Dear Ms. Stiles:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act:

- NDA 10-187 / Supplement 069, dated and received April 10, 2007, for Ritalin (methylphenidate HCl) Tablets
- NDA 18-029 / Supplement 040, dated and received April 10, 2007, for Ritalin SR (methylphenidate HCl) Sustained Release Tablets.
- NDA 21-284 / Supplement 011, dated and received April 6, 2007, for Ritalin LA (methylphenidate HCl) Extended Release Capsules

These "Changes Being Effected" supplemental new drug applications provide for the addition of a Medication Guide as requested in our letter of February 21, 2007 (clarified in our March 19, 2007 email correspondence).

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. The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* For administrative purposes, designate these submissions "**FPL for approved supplement NDA 10-187/S-069, NDA 18-029/S-040, or NDA 21-284/S-011**." Approval of these submissions by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, email Felecia Curtis, RN, Regulatory Project Manager, at Felecia.Curtis@FDA.HHS.GOV.

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 (labeling)

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
4/25/2007 04:41:46 PM