DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-187/S-057, S-058
NDA 18-029/S-028, S-029

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
Associate Director, Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Stiles:

Please refer to your supplemental new drug applications dated January 28, 2000, (S-057 and S-028) and March 10, 2000, (S-058 and S-029) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ritalin (methylphenidate HCL) Tablets and Ritalin SR (methylphenidate HCL) Sustained Release Tablets.

We acknowledge receipt of your amendments dated March 20, 2002, November 26, 2002, and March 21, 2003.

We also refer to our December 14, 2001 and November 19, 2002, approvable letters for these labeling supplements. Your submission of March 21, 2003 constituted a complete response to our November 19, 2002 action letter.

These supplements provide for updates to the "Precautions" section of labeling to include:

1. The addition of statements to the "Carcinogenesis/Mutagenesis/Impairment of Fertility" section.
2. The addition of a pregnancy statement.
3. Addition of statements to the "Pediatric Use" section.

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

In addition we refer to the telephone conversation between you and Richardae Taylor of this Division on March 15, 2004, in which you informed the Division of typographical errors in the submitted labeling text for the above supplements. The errors consisted of the use of the term (b)(4)------ instead of Ritalin in the following sections of labeling, *Pregnancy Category C, Nursing Mothers, and Pediatric Use*. We remind you of your commitment to submit FPL which corrects these errors and replaces the term (b)(4)----- with Ritalin.

The final printed labeling (FPL) must be identical to the package insert submitted on March 21, 2003 including the labeling changes discussed above. Please submit the FPL electronically 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, in no case more

than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 10-187/S-057, S-058 and NDA 18-029/S-028, S-029." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Richardae C. Taylor, Pharm.D., Regulatory Health Project Manager, at (301) 594-5793.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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
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