



NDA 10-187/S-060  
NDA 18-029/S-032

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

Dear Ms. Stiles:

Please refer to your supplemental new drug applications dated March 22, 2001, received March 27, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ritalin® (methylphenidate hydrochloride) and Ritalin-SR Sustained-release Tablets.

These supplemental "Changes Being Effected" new drug applications provide for the following additions to the package insert:

1. Addition of the statement, '*Ritalin is contraindicated during treatment with monoamine oxidase inhibitors, and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result).*' to 'CONTRAINDICATIONS'.
2. Addition of the paragraph, '*Serious adverse events have been reported in concomitant use with clonidine, although no causality for the combination has been established. The safety of using methylphenidate in combination with clonidine or other centrally acting alpha-2 agonists has not been systemically evaluated.*' to 'PRECAUTIONS' 'Drug Interactions'.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (submitted on March 22, 2001). Accordingly, the supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

NDA 10-187/S-060

Page 2

If you should have any questions, please call Ms. Anna Marie Homonnay, R.Ph., Regulatory Health Project Manager, at (301) 594-5535.

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

1/11/02 01:55:00 PM