DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21284 / S-010 **SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation
Attention: Yifeng Jia, Ph.D.
Regional Brand Regulatory Manager
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Jia:

Please refer to your Supplemental New Drug Application (sNDA), dated and received March 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ritalin LA (methylphenidate HCl) Extended-Release Capsules.

We acknowledge receipt of your submission of August 7, 2009, constituting a complete response to our action letter of January 1, 2009.

This Prior Approval sNDA contains revisions to the following sections of the product labeling:

- **CLINICAL PHARMACOLOGY, Pharmacokinetics, *Distribution***
- **CLINICAL PHARMACOLOGY, Pharmacokinetics, *Metabolism***
- **WARNINGS**, *Aggression*
- **PRECAUTIONS, Information for Patients**
- **PRECAUTIONS, Drug Interactions**
- **ADVERSE REACTIONS,** *Vascular*
- **Medication Guide (replacing PPI)**

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, text for the Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Hiren Patel, Pharm.D., Regulatory Project Manager, at Hiren.Patel@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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21284	SUPPL-10	NOVARTIS PHARMACEUTICALS CORP	Ritalin LA) Extended-Release Capsules

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/s/

THOMAS P LAUGHREN
04/27/2010