DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-802/S-001/S-005

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

Dear Ms. Stiles:

We acknowledge receipt of your supplemental new drug applications dated June 16, 2005, received June 17, 2005 (S-001), and March 22, 2006, received March 23, 2006 S-005 (S-005) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Focalin XR (dexmethylphenidate HCl) Extended-Release Capsules.

We additionally acknowledge receipt of your submissions dated February 20, 2006, February 27, 2006, and March 2, 2006 to supplement 001.

Your supplemental new drug application of June 16, 2005 provides for revisions to the **CLINICAL STUDIES-Children and Adolescents** section based on clinical trial data to support a duration of action claim up to 12 hours.

Your supplement of March 22, 2006, submitted as "Changes Being Effected", provides for the addition of a new subsection under **WARNINGS** entitled **Sudden Death and Pre-Existing Structural Cardiac Abnormalities** as requested by the Agency in an Agency communication dated February 14, 2006.

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 agreed-upon (e-mail of April 3, 2006) labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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 supplements NDA 21-802/S-001/S-005**." Approval of these submissions by FDA is not required before the labeling is used.

However, we note that the enclosed labeling also includes changes proposed in your pending "Changes Being Effected" supplemental application (NDA 21-802/S-003), dated November 15, 2005. This supplemental application proposes revisions to the **WARNINGS** and **ADVERSE REACTIONS** sections. Please note that this approval does not apply to the changes proposed in the pending supplemental application. We are currently evaluating the pending application and will comment on the changes in a separate action letter.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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 Susan Player, M.S., A.P.R.N., B.C. Regulatory Project Manager, at (301) 796-1074.

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
4/11/2006 08:00:23 AM