DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-802/S-012

Mara Stiles
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Stiles:

Please refer to your supplemental new drug application dated December 21, 2007, received December 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Focalin XR (dexmethylphenidate hydrochloride) Capsules.

We acknowledge receipt of your submissions dated April 25, 2008 and September 23, 2008.

This supplemental new drug application (NDA 21-802/S-012) provides efficacy data to support a change in labeling in the Clinical Studies section. Treatment with Focalin XR 20 mg per day demonstrated efficacy at the additional time point of 30 minutes (0.5 hour) in children aged 6-12 years with a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD).

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved supplement NDA 21-802/S-012." Approval of this submission 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
Suite 12B05
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 Nicholette Hemingway, Regulatory Project Manager, at (301) 796-1365.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure (Labeling and Medication Guide)

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

10/17/2008 08:06:30 AM