DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-278/S-007

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

Dear Mrs. Stiles:

We acknowledge receipt of your supplemental new drug application dated October 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Focalin (dexmethylphenidate hydrochloride) Tablets.

This "Changes Being Effected" supplemental new drug application provides for additions to the **PRECAUTIONS-Pediatric Use** section to include data from a juvenile neurobehavioral development study in rats which was already included in the Focalin XR (NDA 21-802) product labeling.

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.

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 Felicia Curtis, Regulatory Project Manager, at (301) 796-0877.

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
3/8/2007 01:08:41 PM