DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-121/S-008

McNeil Consumer & Specialty Pharmaceuticals
Attention: Lynn Pawelski
Senior Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Pawelski:

Please refer to your supplemental new drug application dated September 5, 2003, received September 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Concerta® (methylphenidate HCL) Extended-Release Tablets.

We acknowledge receipt of your additional submissions dated:

September 15, 2003	October 13, 2003	February 5, 2004	April 23, 2004
September 23, 2003	December 5, 2003	February 6, 2004	May 4, 2004
September 25, 2003	February 4, 2004	February 9, 2004	May 28, 2004

Your submission of April 23, 2004 constituted a complete response to our March 4, 2004 action letter.

This supplemental new drug application provides for the use of Concerta® (methylphenidate HCL) Extended-Release Tablets in adolescents with attention deficit hyperactivity disorder (ADHD) and to expand labeling to include a 72 mg dose (please note that this is not a new dosage form).

Labeling
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 (text for the package insert).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-121/S-008." Approval of this submission by FDA is not required before the labeling is used.

Pediatric Research Equity Act (PREA)
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.

Promotional Materials
In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

MedWatch
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, HFD-410
FDA
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 Richardae C. Taylor, Pharm.D., Regulatory Project Manager, at (301) 594-2850.

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

Enclosure

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

10/21/04 09:34:35 AM