DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-475/S-002
NDA 21-419/ S-003

Tyco Healthcare/Mallinckrodt
Attention: Ron Groman
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Mr. Groman:

Please refer to your supplemental new drug applications dated February 23, 2006, received February 24, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Methylin (methylphenidate hydrochloride) Chewable Tablets (NDA 21-475) and Methylin (methylphenidate hydrochloride) Oral Solution (NDA 21-419).

Reference is also made to an Agency action letter on the above applications dated May 22, 2006.

We acknowledge receipt of your submissions dated June 15, 2006 (NDA 21-475/S-002 and 21-419/ S-003).

Your submissions of June 15, 2006 constituted a complete response to our May 22, 2006 letter.

These "Changes Being Effected" supplemental new drug applications provide for the following:

- Revisions to the WARNINGS section based upon the recommendations made to the Agency by the members of the Drug Safety and Risk Management Advisory Committee and the Pediatric Advisory Committee.
- Relocated the DRUG ABUSE AND DEPENDENCE section immediately after the WARNINGS section.

We completed our review of these applications, and they are 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
8/10/2006 08:27:49 AM