Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

NDA 21-419/S-001
NDA 21-475/S-004

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

Dear Mr. Groman:

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

We acknowledge receipt of your original supplemental new drug application, NDA 21-475/S-004), and your supplemental application amendment, NDA 21-419, dated March 19, 2007

Reference is also made to an Agency letter and e-mail communication dated February 21, 2007, and March 19, 2007, respectively.

We additionally refer to e-mail communications from you dated May 22, and 30, 2007.

Your responses dated March 19, 2007, May 22, and May 30, 2007, constituted a complete response to our requests dated February 21, 2007, and March 19, 2007.

These supplements, submitted under "Changes Being Effected", provide for the following revisions to labeling:

1. The addition of a Medication Guide.
2. A reference to the Medication Guide in the **PRECAUTIONS-Information for Patients** section.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling texts. Accordingly, these applications are approved effective on the date of this letter.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplements NDAs 21-419/S-001 and 21-475/S-004."

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LT Felecia Curtis, 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

Attachment

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
6/7/2007 04:04:07 PM