DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-163/S-053

Mallinckrodt Inc.
Attention: Russell D. Reed
Labeling Manager, Regulatory Affairs
675 McDonnell Blvd, P.O. Box 5840
St. Louis, MO 63134-0840

Dear Mr. Reed:

Please refer to your supplemental new drug application dated November 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Restoril 7.5 mg, 15 mg, and 30 mg capsules.

Supplemental application S-053, submitted under "Changes Being Effected", provides for the revision of both the prescriber and container labeling to show the changes in name and address of distributor of the drug.

We additionally note that the supplement revises the **Caution: Federal law Prohibits dispensing without prescription** language to **Rx** only and deletes SandoPak information in the **How Supplied** section.

We have completed the review of this supplemental application, 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 submitted final printed labeling (package insert submitted November 29, 2001/Label Code 89014201). Accordingly, this supplemental application is approved effective on the date of this letter.

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 Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

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

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
5/31/02 09:29:01 AM