DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-832/S-022
NDA 17-703/S-018

Abbott Laboratories
Pharmaceutical Products Division
Attention: Lee M. Muraoka
D491/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Mr. Muraoka:

Please refer to your supplemental new drug applications dated May 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act respectively, for Cylert (pemoline) Tablets and Chewable Tablets.

These supplemental applications were submitted under "Changes Being Effected" and provide for revision of the package insert to add a **Geriatric Use** subsection under **PRECAUTIONS**.

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 submitted final printed labeling submitted with these supplemental applications. Accordingly, these supplemental applications are 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 Richardae Taylor, Pharm.D., Regulatory Project Manager, at (301) 594-5793.

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

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