DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-859/SLR-004/SLR-005

Wyeth Pharmaceuticals
Attention: Tracy Rockney
Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Rockney:

Please refer to your supplemental new drug applications dated March 26, 2002 (SLR-004) and December 12, 2002 (SLR-005), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sonata® (zaleplon) Capsules.

We acknowledge receipt of your submission dated March 25, 2003, a complete response to our November 26, 2002 action letter.

We completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 25, 2003.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Melaine Shin, R.Ph., Regulatory Management Officer, 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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