DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-859/S-002/S-003

Wyeth-Ayerst Laboratories
Attention: Timothy Ressler
Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-1245

Dear Mr. Ressler:

Please refer to your supplemental new drug applications dated October 17, 2001 (S-002), and December 6, 2001 (S-003), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sonata (zaleplon) CIV capsules.

Reference is also made to an Agency approval letter dated February 22, 2001 to 20-859/S-001, providing for the use of Sonata capsules for up to 5 weeks (35 nights) for treatment in a controlled trial setting. Our February 22, 2001, letter also requested 20 copies of final printed labeling (FPL) identical to the labeling enclosed with the letter.

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

S-002
This supplement provides for an addition to the **PRECAUTIONS-General** section regarding tartrazine allergic type reactions as well as providing for labeling revisions as requested in the Agency letter dated February 22, 2001.

S-003
This supplement provides for a correction to the **ADVERSE REACTIONS/Adverse Findings Observed in Short-Term, Placebo-Controlled Trials** section to reflect the labeling approved in our February 22, 2001 Agency letter.

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 (package insert submitted December 6, 2001/Label Code CI 6001-3). 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 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
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