DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-859/S-009, S-011

King Pharmaceuticals, Inc.
Jones Pharma subsidiary
501 Fifth Street
Bristol, TN 37620

Attention: Douglas J. Dewar, Ph.D.
Senior Director, Drug Regulatory Affairs

Dear Dr. Dewar:

Please refer to your supplemental new drug applications noted below under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sonata (zaleplon) 5 mg and 10 mg capsules.

Application	Submitted on:	Received on:	Provides for:
S-009	March 27, 2007	March 28, 2007	"Changes being Effected" Supplement; revisions to Warnings and Precautions section
S-011	August 10, 2007	August 13, 2007	"Prior Approval" Supplement: Medication Guide

We also acknowledge receipt of your submissions dated November 21, 2006, August 10, 2007, and November 28, 2007.

The S-009 "Changes Being Effected" supplemental new drug application provides for changes to the package insert in response to the Agency's February 14, 2006 and December 5, 2006 letters requesting a class labeling change for the sedative-hypnotic drug group. The S-011 "Prior Approval" supplemental new drug application provides for the provision of a Medication Guide. These supplemental new drug applications (S-009 and S-011) constitute a complete response to our December 5, 2006 action letter.

We completed our review of these two supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and medication guide submitted on November 1, 2007).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate of this

submission "**FPL for approved supplement NDA 20-859 S-009, S-011**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit revised content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at the following website: http://www.fda.gov/oc/datacouncil/spl.html

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the revised product labeling and has determined that it contains significant new risk information relating to your drug product. We are hereby requesting that all promotional materials for your drug product that include representations about your drug product be revised to include the new risk information immediately. These revisions should include prominent disclosure of the important new information described in the WARNINGS and PRECAUTIONS sections that appear in the revised package labeling. Please submit a written response to this request on or before November 28, 2007, stating whether you intend to comply with this request to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Cathleen Michaloski, MPH, Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}
Russell G. Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

Enclosure: Approv Labeling 20-859/S-009, S-011

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

12/11/2007 02:11:34 PM