DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-529/S-009
NDA 17-530/S-018
NDA 17-531/S-010

King Pharmaceuticals, Inc.
Attention: Dean R. Cirotta, MBA
Senior Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Cirotta:

Please refer to your new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tigan (trimethobenzamide hydrochloride) 100 and 200 mg suppositories (NDA 17-529), 200 mg/2 ml injection (NDA 17-530), and 300 mg capsules (NDA 17-531).

Reference is also made to an Agency letter dated December 13, 2001, providing for the approval of supplemental application 17-531/S-010.

We additionally refer to your labeling supplements, NDAs 17-529/S-009 & 17-531/S-018, dated December 19, 2001, submitted under "Changes Being Effected", providing for revisions to the labeling in accordance with the Agency letter dated December 13, 2001.

We have completed the review of these supplemental applications, NDAs 17-529/S-009 & 17-531/S-018, 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 19, 2001/Label Code 0934128). Accordingly, these supplemental applications are approved effective on the date of this letter.

Additionally, we acknowledge receipt of your submission to NDA 17-531/S-010 dated January 18, 2002, providing for 20 copies of FPL as requested in our approval letter dated December 13, 2001.

We have completed our review of the labeling (Label Code 0934128) submitted on January 18, 2002, and it is acceptable. Therefore, this labeling will be retained in our files.

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
4/30/02 08:06:00 AM