DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-531/S-013

King Pharmaceuticals, Inc.
Attention: Tom W. Der
Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Der:

Please refer to your supplemental new drug application dated April 30, 2008, received May 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tigan (trimethobenzamide hydrochloride) capsules, 300 mg.

We acknowledge receipt of your submissions dated October 15, 2008; October 28, 2008; and November 7, 2008.

This supplemental new drug application provides for inclusion of information regarding the metabolic fate of trimethobenzamide in the package insert label. In addition, this application addresses the following postmarketing commitment from NDA 17-531/S-010, approved on December 13, 2001:

- Study Commitment #1: Provide additional information regarding the metabolic fate of trimethobenzamide for labeling purposes.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. We also conclude that the above postmarketing commitment was fulfilled.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). These revisions are terms of the approval of this application. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplement NDA 17-531/S-013**."

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert Label

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Donna Griebel

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