DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-531/S-010

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

Dear Mr. Cirotta:

Please refer to your supplemental new drug application dated February 8, 2001, received February 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tigan® (trimethobenzamide hydrochloride) Capsules, 300 mg.

This supplemental new drug application provides for the following in response to the Federal Register notice of January 9, 1979, classifying this drug effective for postoperative nausea and vomiting and nausea associated with gastroenteritis: draft labeling, results of bioavailability studies, and updated manufacturing and controls and testing procedures.

We have completed the review of this supplemental application, and it is approved. This action approves this application on the basis of effectiveness of the drug as well as safety. This action also approves those supplemental applications that were permitted under the provisions of 21 CFR 314.70 and have not been superceded.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-531/S-010." Approval of this submission by FDA is not required before the labeling is used.

The agreed upon approved dissolution specifications are listed below:

Apparatus:	USP Apparatus I (baskets) rotated at 100 rpm
Dissolution medium:	900 ml of water at 37±0.5° C
Proposed specification:	NLT(b)((Q) is dissolved in 30 minutes.

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We remind you of your post marketing study commitment dated November 8, 2001, as listed below:

1. Provide additional information regarding the metabolic fate of trimethobenzamide for labeling purposes.

Please submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

We also note your agreement to circulate a "Dear Health Care Professional" letter to alert the healthcare community about the new 300 mg capsule strength. We also request that you submit a copy of the final letter to this NDA and a copy to the following address:

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

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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., Project Manager, at (301) 594-5793.

Sincerely,

{See appended electronic signature page}
Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure