DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-530/S-021, S-022, S-023

King Pharmaceuticals, Inc.
Attention: Greg Carrier
Vice President, Regulatory Affairs
501 5th Street
Bristol, TN 37620

Dear Mr. Carrier:

Please refer to your supplemental new drug applications dated May 13, 2005, received May 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tigan® (trimethobenzamide hydrochloride) Injection. Your May 13, 2005 submission constituted a complete response to our March 24, 2005 action letter.

We acknowledge receipt of your submission dated July 20, 2005.

These supplemental new drug applications provides for the following:

- S-21: a change to a preservative-free (PF) formulation
- S-22: a container-closure system from ampule to vial
- S-23: a change in manufacturing processes

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels).

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 these submissions "**FPL for approved supplement** NDA 17-530/S-021, S-022, S-023." Approval of these submissions by FDA is not required before the labeling is used.

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 Giuseppe Randazzo, Consumer Safety Officer, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
DNDC DNDCII, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

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

/s/

Liang Zhou

8/26/2005 12:01:00 PM