DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 17, 2001

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

Re: Docket Nos. 78N-0224 & 78N-0227;
DESI No. 11853

Dear Mr. Cirotta:

Enclosed is a copy of the signed agreement intended to resolve outstanding regulatory issues concerning Tigan (trimethobenzamide hydrochloride) drug products manufactured by King Pharmaceuticals, Inc. Mr. Parker and Mr. Landa have added their signatures to that of Mr. Gregory, so the agreement is fully executed.

I greatly appreciate your willingness to work with us in resolving the Tigan issues. If you have any questions related to the agreement, please feel free to call me at 301-594-5649.

Sincerely,

Brian Pendleton

Brian L. Pendleton
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

78N-0224

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

In the Matter of:	)	
	)	
Tigan Suppositories, Injection, & Capsules	)	Docket Nos. 78N-0224 & 78N-0227
	)	DESI No. 11853
	)	

AGREEMENT

The Center for Drug Evaluation and Research (CDER) of the United States Food and Drug Administration (FDA) and King Pharmaceuticals, Inc. (King), agree to take the following actions regarding the drug products Tigan (trimethobenzamide hydrochloride) Suppositories, Injection, and Capsules:

1. King shall, within ten days of the date that this agreement is executed by all the parties, submit written notification to FDA's Dockets Management Branch withdrawing its request for a hearing on matters related to New Drug Applications (NDAs) 17-529 (Tigan Suppositories), 17-530 (Tigan Injection), and 17-531 (Tigan Capsules), and all amendments and supplements thereto, submitted in response to the notices of opportunity for hearing (NOOHs) published at 44 Fed. Reg. 2017 & 2021 (1979).

2. *Suppositories (NDA 17-529).* a. King shall submit to FDA, by December 2, 2002, a supplement to NDA 17-529 containing the results of a study or studies intended to support the marketing of a Tigan suppository product.

b. If King fails to submit such a supplement to NDA 17-529 by the date specified in the previous paragraph, or if FDA, after reviewing the supplement, informs King that the supplement does not support the marketing of a Tigan suppository product, FDA shall, as it deems appropriate, withdraw approval of NDA 17-529.

3. *Injection (NDA 17-530).* a. King shall submit to FDA, within thirty days after the date on which FDA issues its decision on the supplement for a 300 mg Tigan capsule product specified in Section 4 of this agreement, a supplement to NDA 17-530 that is intended to support the marketing of a Tigan injection product.

b. If King fails to submit such a supplement, or if FDA determines that the supplement is deficient in any respect, FDA shall, as it deems appropriate, withdraw NDA 17-530.

4. *Capsules (NDA 17-531).* a. King has submitted to FDA a supplement to NDA 17-531, dated February 8, 2001, and received by FDA on February 23, 2001, containing a bioequivalence study intended to support the marketing of a 300 mg Tigan capsule product.

b. If FDA, after reviewing the supplement, informs King that the supplement does not support the marketing of a 300 mg Tigan capsule product, FDA shall, as it deems appropriate, withdraw approval of NDA 17-531.

5. Following final resolution of the issues covered by this agreement, FDA shall publish an appropriate notice in the *Federal Register* stating, among other things, that any trimethobenzamide hydrochloride drug product marketed without an application approved under section 505 of the Federal Food, Drug, and Cosmetic Act is subject to FDA regulatory action.

6. All decisions made by FDA pursuant to, or flowing from, this agreement, including but not limited to any decision regarding the validity or adequacy of any study design or results submitted to FDA, and any decision regarding the approval, sufficiency, timeliness, or adequacy of any NDA, NDA supplement, or other submission made to FDA pursuant to this agreement, shall be vested in the complete discretion of the Agency. King waives all appeals, administrative or judicial, of any FDA decisions made pursuant to, or flowing from, this agreement, except that any decision made by FDA's Division of Neuropharmacological Drug Products may be appealed to the Director of that division.

Dated: August 14th 2001

Agreed to as to form and contents:

Jefferson Gregory
President and Chief Operating Officer
King Pharmaceuticals, Inc.

August 16, 2001

Neal B. Parker, Esq.
Associate Chief Counsel, United States Food and Drug Administration
Counsel for Center for Drug Evaluation and Research

The United States Food and Drug Administration, Department of Health and Human Services, accepts this agreement.

Dated: August 16, 2001

Michael M. Landa, Esq.
Acting Chief Counsel, United States Food and Drug Administration
Counsel for Commissioner of Food and Drugs