78N-0224

King Pharmaceuticals, Inc.
501 Fifth Street
Bristol, Tennessee 37620

1-800-336-7783
1-423-989-8001
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August 15, 2001

Dean R. Cirotta, MBA
Senior Director, Regulatory Affairs

VIA FEDERAL EXPRESS

David T. Read, Director
Division of Regulatory Policy I, HFD-7
Office of Regulatory Policy
Center for Drug Evaluation and Research
U.S. FOOD AND DRUG ADMINISTRATION
1451 Rockville Pike
Rockville, MD 20852

Re: Approved Agreement for Tigan Applications NDAs 17-529, 17-530 & 17-531

Dear Mr. Read:

Per your request, I have enclosed the Tigan agreement, which has been signed by Jefferson Gregory, King's President and COO. Per section 1 of the agreement King will withdraw its request for a hearing once The FDA approves the agreement and I receive a copy of the fully executed agreement.

I would like to take this opportunity to thank you for your time and the cooperation in reaching this agreement. We very much appreciate your willingness to work with us in developing a plan and timeline that will result in approved applications for the Tigan products.

Please direct any communications regarding this agreement to my attention at the above address, or I may be reached by telephone at (423) 274-8663, or via FAX at (423) 989-8055.

Sincerely,
KING PHARMACEUTICALS, INC.,

Dean R. Cirotta
Senior Director, Regulatory Affairs

CC: Jefferson Gregory, President and COO, King Pharmaceuticals, Inc.
Thomas K. Rogers, Executive Vice President, Regulatory Affairs, King Pharmaceuticals, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 7 2001

Food and Drug Administration
Rockville MD 20857

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 an agreement intended to resolve outstanding regulatory issues concerning Tigan (trimethobenzamide hydrochloride) drug products manufactured by King Pharmaceuticals, Inc. (King).

The agreement states, among other things, that King will, within 10 days of the date that the agreement is fully executed, withdraw its request for a hearing on matters related to NDA 17-529 (Tigan Suppositories), NDA 17-530 (Tigan Injection), and NDA 17-531 (Tigan Capsules). The agreement also states that King will submit to the Food and Drug Administration (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. In addition, King will submit a supplement to NDA 17-530 that is intended to support the marketing of a Tigan injection product. This supplement will address labeling issues for Tigan Injection. King will submit this supplement within 30 days after the date on which FDA issues its decision on the pending supplement to NDA 17-531 for a 300 mg Tigan capsule product.

The agreement also requires FDA, following resolution of the issues addressed in the agreement, to publish a 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.

If the terms of the agreement are acceptable, please have Mr. Gregory sign the document and return it to me for signing by Mr. Parker and Mr. Landa of FDA's Office of the Chief Counsel. When the agreement is fully executed, I will send you a copy of the final document. If you have any questions about the agreement, please feel free to call me at 301-594-5605 or Brian Pendleton at 301-594-5649.

Sincerely,

David T. Read
Director
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

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.

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: _____

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