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

1-800-336-7783
1-423-989-8001
Fax: 1-423-989-6113

August 24, 2001

Dean R. Cirotta, MBA
Senior Director, Regulatory Affairs

VIA FEDERAL EXPRESS

Dockets Management Branch
U.S. FOOD AND DRUG ADMINISTRATION
HFA-305, Room #1061
5630 Fishers Lane
Rockville, MD 20852

Re: Tigan Applications NDAs 17-529 (Suppository), 17-530 (Injection) & 17-531 (Capsules)
Docket Nos. 78N-0224 & 78N-0227
DESI No. 11853

Dear Mr. Read:

Per Section 1 of our Tigan agreement, executed on August 16, 2001 (see Attachment 1), King Pharmaceuticals hereby withdraws the request for a hearing on matters related to the above named NDAs, submitted on January 30, 1979 by Alan H. Kaplan on behalf of Beecham Laboratories (see Attachment 2), which was filed in response to the notices of opportunity for hearing (NOOHs) published at 44 Fed. Reg. 2017 & 2021 (January 9, 1979). King purchased these NDAs from Roberts Pharmaceuticals on 11/12/99.

This withdrawal is being filed within 10 days of the execution of the Tigan agreement in compliance with the requirements of Section 1.

Please direct any communications regarding this withdrawal 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.
David T. Read, Esq., Director, Division of Regulatory Policy I

78N-0224

WDL 1

ATTACHMENT #1

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

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

ATTACHMENT #2

VINCENT A. KLEINFELD
ALAN H. KAPLAN
ROBERT H. BECKER
THOMAS O. HENTELEFF
RICHARD S. MOREY
PETER O. SAFIR
F. KAID BENFIELD
GLENN E. DAVIS
MARC H. SHAPIRO
CHARLES H. BARR

LAW OFFICES
KLEINFELD, KAPLAN AND BECKER
1200 SEVENTEENTH STREET, N. W.
WASHINGTON, D. C. 20036

TELEPHONE
(202) 659-2155

January 30, 1979

Hearing Clerk
Food and Drug Administration (HFC-20)
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20857

Re: NDA 17-529 TIGAN Suppositories Docket No. 78N-0224

NOTICE OF APPEARANCE AND REQUEST FOR HEARING

Dear Sir:

The Federal Register of January 9, 1979, (43 Fed. Reg. 2021-22,) carried a Notice that the Director of the Bureau of Drugs proposed to issue an order withdrawing approval of NDA 17-529 covering suppositories of trimethobenzamide. The Notice further provided applicant with an opportunity for a hearing on the Director's proposal.

Please be advised that the undersigned, on behalf of Beecham Laboratories, a division of Beecham Inc., requests a hearing on the proposed withdrawal of approval for NDA 17-529 and Supplements thereto.

As provided in the applicable regulations, Beecham Laboratories will forward on or before March 12, 1979, the data, information and analysis upon which it relies to justify a hearing.

Very truly yours,

Alan H. Kaplan
Attorney for Beecham, Inc.

VINCENT A. KLEINFELD
ALAN H. KAPLAN
ROBERT H. BECKER
THOMAS O. HENTELEFF
RICHARD S. MOREY
PETER O. SAFIR
F. KAID BENFIELD
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KLEINFELD, KAPLAN AND BECKER
1200 SEVENTEENTH STREET, N. W.
WASHINGTON, D. C. 20036

TELEPHONE
(202) 659-2155

January 30, 1979

Hearing Clerk
Food and Drug Administration (HFC-20)
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20857

Re: NDA 17-530 TIGAN Injection Docket No. 78N-0227
NDA 17-531 TIGAN Capsules

NOTICE OF APPEARANCE AND REQUEST FOR HEARING

Dear Sir:

The Federal Register of January 9, 1979, (43 Fed. Reg. 2017-20,) carried a Notice that the Director of the Bureau of Drugs proposed to issue an order withdrawing approval of certain product claims approved under NDA 17-530 and NDA 17-531. The Notice further provided applicant with an opportunity for a hearing on the Director's proposal.

Please be advised that the undersigned, on behalf of Beecham Laboratories, a division of Beecham, Inc., requests a hearing on the proposed withdrawals.

As provided in the applicable regulations, Beecham Laboratories will forward on or before March 12, 1979, the data, information and analysis upon which it relies to justify a hearing.

Very truly yours,

Alan H. Kaplan

Alan H. Kaplan
Attorney for Beecham, Inc.

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KING PHARMACEUTICALS INC
501 5TH ST
BRISTOL TN 37620
(423)989-6200

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ROCKVILLE MD 20852

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