

THOMAS O. HENTELEFF
RICHARD S. MOREY
KINSEY S. REAGAN
PETER R. MATHERS
ANTHONY L. YOUNG
ANNE V. MAHER
BONNIE A. BEAVERS
DANIEL R. DWYER
GLENN E. DAVIS
STACY L. EHRLICH
JENNIFER A. DAVIDSON
STACEY L. VALERIO
ROBERT O. WINTERS

OF COUNSEL:
HARVEY A. SUSSMAN
WILLIAM J. HARDY

LAW OFFICES
KLEINFELD, KAPLAN AND BECKER, LLP

1140 NINETEENTH STREET, N.W.
WASHINGTON, D. C. 20036-6606
TELEPHONE (202) 223-5120
FACSIMILE (202) 223-5619
www.kkblaw.com

WEST COAST OFFICE:
ONE MARKET STREET
STEUART TOWER, SUITE 1450
SAN FRANCISCO, CA 94105-1313
TELEPHONE (415) 538-0014
FACSIMILE (415) 538-0016

VINCENT A. KLEINFELD
1907-1993

ALAN H. KAPLAN
1930-2001

March 18, 2004

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

PETITION FOR STAY OF ACTION

On behalf of King Pharmaceuticals, Inc. ("King"), the undersigned submit this petition under 21 C.F.R. § 10.35 to request that the Commissioner of Food and Drugs ("Commissioner") stay approval of any generic metaxalone products until the Agency has fully evaluated and ruled upon King's contemporaneously filed March 18, 2004 Citizen Petition. In its Citizen Petition, King requests that the Commissioner: (a) rescind the March 1, 2004 'Dear Applicant' Letter issued by the Director of the Office of Generic Drugs regarding metaxalone labeling ("March 1, 2004 Letter"); (b) require applicants seeking approval to market generic metaxalone products that rely on King's SKELAXIN® as the reference listed drug to submit a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) on U.S. Patent No. 6,407,128; and (c) prohibit the removal from generic metaxalone labeling of the pharmacokinetic information that appears in the SKELAXIN® labeling. The basis for this Petition for Stay is set forth below, and in King's March 18, 2004 Citizen Petition, incorporated herein by reference.

2004 P-0140

PSA 1

KLEINFELD, KAPLAN AND BECKER, LLP

Petition for Stay of Action
March 18, 2004
Page 2

Decision Involved

The decisions that are the subject of this Petition for Stay of Action are possible final approvals of any and all ANDAs for metaxalone that list SKELAXIN® as the reference listed drug.

Action Requested

King requests that FDA stay approval of any generic metaxalone products until the Agency has fully evaluated and ruled upon King's March 18, 2004 Citizen Petition. The need for dispatch in this case is particularly acute because the March 1, 2004 Letter expresses ill-considered, unfounded, and contrary-to-law conclusions that could result in issuance of inappropriate final approvals of generic metaxalone products at any time.

Statement of Grounds

Under 21 C.F.R. § 10.35(e), FDA must grant a stay of action if all of the following criteria are met:

- (1) the petitioner will otherwise suffer irreparable injury;
- (2) the petitioner's case is not frivolous and is being pursued in good faith;
- (3) the petitioner has demonstrated sound public policy grounds supporting the stay; and
- (4) the delay resulting from the stay is not outweighed by public health or other public interests.

KLEINFELD, KAPLAN AND BECKER, LLP

Petition for Stay of Action
March 18, 2004
Page 3

As demonstrated below, all of these criteria are met here, and a stay should therefore be granted.

King faces imminent, substantial and irreparable injury in the absence of a stay. King holds the original NDA for SKELAXIN® (metaxalone). Under the 1984 amendments to the Federal Food, Drug and Cosmetic Act, the incentives for pioneer manufacturers such as King to devote the substantial resources required to develop pioneer products are preserved by carefully crafted protections against “me too” approvals (*i.e.*, ANDAs and Section 505(b)(2) applications) for directly competing versions of the pioneer products. These protections include patent certification procedures that ensure pioneer manufacturers the right to challenge potential infringement prior to effective approval of competing products.

As explained in detail in King’s March 18, 2004 Citizen Petition, these protections may be eviscerated if generic applicants are permitted to omit critical pharmacokinetic information describing the relative bioavailability of metaxalone with food compared to without food from their labeling and correspondingly, and submit a ‘section viii statement’ in lieu of a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii), to the patent covering SKELAXIN® and listed in the Orange Book. As a consequence, the potentially imminent approval of generic metaxalone products threatens to immediately and irreparably erode King’s legally appropriate, exclusive sales position without its competitors’ compliance with the requisite legal safeguards.

KLEINFELD, KAPLAN AND BECKER, LLP

Petition for Stay of Action

March 18, 2004

Page 4

The nature of this injury is substantial and irreparable. In particular, injuries include, among numerous others: (1) immediate and substantial lost sales of SKELAXIN® and the revenue therefrom, (2) a swift and irrecoverable erosion in the price of SKELAXIN® as King is forced to compete with generic competitors' prices, and (3) immediate and substantial disruption of the important educational and promotional functions of King's sales force as they are forced to turn their efforts to unjustified competitive issues.

Moreover, if generic metaxalone products are approved based on FDA's March 1, 2004 Letter, they will be approved with inadequate and incomplete labeling that renders administration of the generic products less safe and effective than SKELAXIN®. King has a strong interest in ensuring that metaxalone products are used safely and effectively. Any safety or efficacy problems associated with metaxalone will taint the marketplace, King's reputation, and the reputation of King's SKELAXIN®, and will negatively impact sales of SKELAXIN®. This is particularly true because these improperly labeled generic products may be freely substituted for SKELAXIN®.

Like the loss to plaintiffs in Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 29 (D.D.C. 1997) (citation omitted), the loss to King in the absence of a stay would be without "adequate compensatory or other corrective relief" that can be provided at a later date, tipping the balance in favor of [the]...relief." Furthermore, in the absence of a stay pending resolution of the important substantive, scientific, legal, and procedural issues

KLEINFELD, KAPLAN AND BECKER, LLP

Petition for Stay of Action

March 18, 2004

Page 5

raised in the Citizen Petition, currently pending patent litigation could be terminated, impeded, or mooted, final approvals may be issued, and existing priority rights may be violated based on the flawed conclusions stated in the March 1, 2004 Letter. Without a stay, such actions as may subsequently be found to have been inappropriate may, at that point, be impossible to effectively or efficiently redress.

Second, King's case is strong, simple, and compelling, is not frivolous, and is being pursued in good faith. In the contemporaneously filed Citizen Petition, King has raised serious and substantial questions regarding the scientific, medical, policy, and legal propriety of FDA's March 1, 2004 Letter.

Third, sound public policy grounds support the stay. It is directly contrary to the interest of physicians and consumers to approve a drug product with labeling that renders administration of the product less safe and effective. Moreover, implementation of a dramatic change in policy such as that reflected in the March 1, 2004 Letter should be accomplished only after due consideration of the views of the many affected parties. Issuance of a stay as requested herein would ensure that such consideration can proceed on a timely basis.

Finally, any delay resulting from the stay is not outweighed by public health or other public interests. "The public's interest in 'the faithful application of the laws' outweigh[s] its interest in immediate access to [a competing] product." Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998). This is

KLEINFELD, KAPLAN AND BECKER, LLP

Petition for Stay of Action

March 18, 2004

Page 6

particularly true when, as here, the 1984 amendments to the Federal Food, Drug and Cosmetic Act provide that King should be afforded the opportunity to challenge potential infringement prior to effective approval of competing products.

FDA regulations also authorize the agency to grant a discretionary stay if it "is in the public interest and in the interest of justice." 21 C.F.R. § 10.35(e). Both the public interest and the interest of justice support King's request for a stay. If FDA does not believe it necessary to issue a mandatory stay, it should issue a discretionary stay.

Conclusion

For the reasons set forth above, the undersigned submit that the Commissioner should stay approval of any generic metaxalone products until the Agency has fully evaluated and ruled upon King's March 18, 2004 Citizen Petition.

Respectfully submitted,



Peter R. Mathers

Stacy L. Ehrlich

Jennifer A. Davidson

KLEINFELD, KAPLAN AND BECKER, LLP

1140 19th Street, NW

Washington, DC 20036

202-223-5120

Counsel for King Pharmaceuticals, Inc. and
Jones Pharma Inc.