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September 17, 2004

BY HAND DELIVERY

Lester M Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs
c/o Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Petition for Reconsideration
Docket Nos. 2003P-0126/CP1, 2003P-0387/CP1

Dear Dr. Crawford:

On behalf of Jones Pharma, Inc. (Jones), a subsidiary of King Pharmaceuticals, Inc., and the manufacturer of Levoxyl® (levothyroxine sodium, USP) tablets, we write to support the July 23, 2004 Petition for Reconsideration filed on behalf of Abbott Laboratories (Abbott). That Petition, submitted to Food and Drug Administration (FDA) Docket Nos. 2003P-0387/CP1 and 2003P-0126/CP1, seeks reconsideration of the Agency's June 23, 2004 decision denying Abbott's and Jones's requests that the Agency establish appropriate bioequivalence standards prior to making any determination as to the bioequivalence of approved levothyroxine sodium products and before approving any generic levothyroxine sodium products. We write separately to explicitly support reconsideration of that decision insofar as it denied Jones's Citizen Petition. See FDA Docket. No. 2003P-0126/CP1.

As the submissions from leading endocrinology organizations in support of Abbott's Petition for Reconsideration illustrate, FDA's decision to approve "substitutable" generic levothyroxine sodium products continues to be a matter of grave concern to clinicians and patients, as well as the industry. The Agency's decision to deny Abbott's and Jones's requests for a public meeting to evaluate appropriate methodologies for establishing bioequivalence between levothyroxine sodium tablet drug products, however, deprived interested parties an appropriate forum in which to voice those concerns. Jones thus joins in Abbott's request that the Agency reconsider its decision to refuse to convene a public meeting.

Jones likewise supports Abbott's request that FDA reconsider the methodology it used to approve generic levothyroxine drug products and to establish bioequivalence among approved

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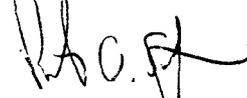
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levothyroxine products. The scientific evidence presented in Abbott's citizen petition demonstrates that levothyroxine bioequivalence testing raises clinical, study design, and statistical challenges. FDA's current methodology, which would deem levothyroxine products differing in bioavailability from the reference product by 9, 12.5 and 15 percent as "bioequivalent" to the reference product, fails to adequately address those challenges. Jones thus urges FDA to refrain from approving additional generic levothyroxine tablet products and assigning "A" therapeutic equivalence ratings to other products before it has convened a public meeting to consider these challenges and has adopted a more appropriate bioequivalence standard.

Respectfully submitted,



Peter O. Safir

cc: Thomas K. Rogers, III, EVP & Corporate Head, Regulatory Affairs, King
Pharmaceuticals, Inc.
William K. Hubbard, Associate Commissioner for Policy and Planning, FDA
Daniel E. Troy, Chief Counsel, FDA
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