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Via Facsimile & U. S. Mail

Daniel Troy
Chief Counsel
Food and Drug Administration
Room 657 (GCF-1)
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Troy:

We are writing to respond briefly to Jonathan W. Emord's letter of September 24, 2002, sent to you regarding the May 23, 2002 Comment (the "Comment") filed by King Pharmaceuticals, Inc. ("King") with respect to the Petition for Stay of Action (the "Petition") filed by Jerome Stevens Pharmaceuticals, Inc. ("Jerome"), Docket No. 02P1035. 1/

Most importantly, we note that Jerome does not contest the fundamental factual and legal reasons why the FDA should not take any action with respect to the Levoxyl® NDA presented in King's Comment. Jerome still does not specifically request that the FDA "stay" or suspend its prior approval of the Levoxyl® NDA, or make any allegation that Jerome's purported trade secrets are implicated in the Levoxyl® NDA. Given that the Levoxyl® NDA was filed weeks before the FDA's alleged disclosure of Jerome's manufacturing information, Jerome cannot suggest that the formula and manufacturing process set forth in the Levoxyl® NDA were somehow derived from Jerome's later-disclosed information.

With respect to Mr. Emord's challenge to two of the legal points set forth in King's Comment, we note the following:

(1) While King itself takes no position on the issue, it is our understanding that the FDA has interpreted 21 C.F.R. § 10.20(j) to require that petitions submitted under 21 C.F.R. § 10.30, including all supporting material and

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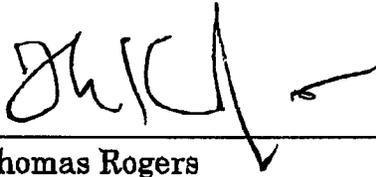
1/ Notwithstanding Mr. Emord's erroneous assertion, King's Comment was unquestionably authorized by 21 C.F.R. §§10.30(d) and 10.35(h)(3).

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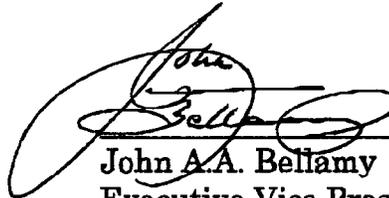
information that the petitioner wants the FDA to consider, be on public display and available for public inspection; and

(2) Mr. Emord's letter fails to recognize the distinction, set forth in 21 U.S.C. § 355(e), between the factual finding of imminent hazard to the public health necessary for the immediate suspension of FDA approval of an NDA 2/ versus the factual findings necessary before approval of an NDA may, after notice and opportunity for the applicant to be heard, be withdrawn by the FDA. This distinction is properly addressed in King's Comment, and we stand by our analysis.

Thus, King renews its request that Jerome's Petition be denied with respect to the Levoxyl® NDA. Furthermore, to the extent the FDA is inclined to consider Mr. Emord's comments, we request that his letter, and this response, be included in Docket No. 02P1035.



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2/ FDA approval of an NDA can only be suspended, without notice and opportunity for hearing to the applicant, upon a finding by the Secretary of HHS of an "imminent hazard to the public health." 21 U.S.C. § 355(e). The "authority conferred by this proviso to suspend the approval of an application shall not be delegated." *Id.*