DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Docket No. 97N-0314/CP4

Dear Mr. Scheineson:

This letter responds to your petition dated November 17, 2000, submitted on behalf of Jerome Stevens Pharmaceuticals, Inc. (JSP). Your petition requests that the Food and Drug Administration (FDA) refuse to extend further the deadline for manufacturers of orally administered levothyroxine sodium drug products to obtain approved new drug applications (NDAs) as a condition for continuing to market their products.

On August 14, 1997, FDA published a *Federal Register* notice announcing that orally administered levothyroxine sodium drug products are new drugs and require approved applications as a condition of marketing (62 FR 43535). Because of the medical necessity of levothyroxine sodium, the notice provided that manufacturers who were marketing levothyroxine sodium products on or before August 14, 1997, could continue to market their products without approved applications until August 14, 2000. A subsequent *Federal Register* notice extended this date to August 14, 2001 (65 FR 24488; April 26, 2000).

JSP submitted NDA 21-210 for levothyroxine sodium on October 19, 1999. The NDA was approved on August 21, 2000, and JSP's product, Unithroid, is currently the only approved levothyroxine sodium product. You state that JSP has expanded its production capabilities and is capable of meeting the entire domestic demand for levothyroxine sodium. Therefore, you suggest, "[t]he concern that thyroid patients would lose a medically necessary treatment if FDA enforced the NDA requirement no longer applies" (Petition at 3).

At present, the August 14, 2001, deadline remains in place, and FDA has no plans to extend the date by which levothyroxine sodium products must have approved applications. However, unforeseen circumstances could arise that would make an extension appropriate, and the Agency, therefore, will not foreclose that possibility. For this reason, your petition requesting an agency commitment to refuse to extend the deadline is denied at this time.

Sincerely yours,

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

97N-0314

PDN