DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 16 2003

6257 '03 SEP 23 P1:30

Thomas K. Rogers, III
Global Head, Regulatory Affairs
King Pharmaceuticals, Inc. and its
subsidiary Jones Pharma, Inc.

Peter O. Safir, Esq.
Scott L. Cunningham, Esq.
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004-2401

Docket No. 03P-0126/CP1

Dear Messrs. Rogers, Safir, and Cunningham:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated March 28, 2003, on behalf of Jones Pharma Inc. concerning the appropriate bioequivalence methodology for levothyroxine sodium tablets.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2003P-0126

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