



SEP 7 2004

Food and Drug Administration
Rockville MD 20857

Peter R. Mathers, Esq.
Stacy L. Ehrlich, Esq.
Jennifer A. Davidson, Esq.
Kleinfeld, Kaplan and Becker, LLP
1140 Nineteenth Street, N.W.
Washington, D.C. 20036

Re: Docket No. 2004P-0140/CP1

Dear Mr. Mathers, Ms. Ehrlich, and Ms. Davidson:

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 18, 2004, submitted on behalf of King Pharmaceuticals, Inc. (King). Your petition requests that FDA: (1) rescind the March 1, 2004, "Dear Applicant" letter issued by the Director of the Office of Generic Drugs concerning metaxalone labeling, (2) 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, and (3) prohibit the removal from generic metaxalone labeling of the pharmacokinetics information that appears in the Skelaxin labeling.

FDA has been unable to reach a decision on your petition because it raises complex 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 requests.

Sincerely,

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

2004P-0140

LET 2