DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Arthur Y. Tsien, Esq.
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Olsson, Frank and Weeda, P.C.
Suite 400
1400 Sixteenth Street, N.W.
Washington, D.C. 20036-2220

Docket No. 03P-0027/CP1

Dear Mr. Tsien and Dr. Strobos:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on January 28, 2003, on behalf of Eon Labs, Inc. Your petition requests that the Agency restore the labeling for Skelaxin (metaxalone tablets) that was approved as of May 31, 2002; or in the alternative, determine that the May 31, 2002, labeling was not withdrawn for safety or effectiveness reasons. Your petition also asks FDA to take various actions that would remove obstacles standing in the way of approval of generic versions of Skelaxin.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

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

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