DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 13 2007

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Roland Gerritsen van der Hoop, M.D., Ph.D.
Senior Vice President of Research and
Development and Regulatory Affairs
Endo Pharmaceuticals
100 Painters Drive
Chadds Ford, PA 19317

Re: Docket No. 2006P-0522/CP1

Dear Dr. Gerritsen van der Hoop:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on December 18, 2006. Your petition requests that the Agency require any abbreviated new drug application referencing Lidoderm (lidocaine topical patch, 5%) to conduct comparative clinical efficacy trials to demonstrate bioequivalence.

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 request.

Sincerely,

Jane A. Axelrad

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

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