



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

December 18, 2006

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

Dear Dr. van der Hoop:

Your petition requesting the Food and Drug Administration to apply bioequivalence requirements consistent with 21 CFR 320.24(b)(4) to any ANDA seeking approval as a generic drug using Lidoderm as its reference listed drug, was received by this office on 12/18/2006. It was assigned docket number 2006V-0522/CP1 and it was filed on 12/18/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2006P-0522

ACK 1