DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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November 15, 2013

Peter R. Mathers
Counsel to Purdue Pharma L.P.
Kleinfield, Kaplan, and Becker, LLP
1140 Nineteenth Street N.W.
Washington, D.C. 20036

Dear Mr. Mathers:

Your petition to the Food and Drug Administration requesting the Agency to adopt and announce a guidance detailing in vitro and in vivo tests sufficient to establish that proposed generic products have equivalent abuse-deterrent properties and can be expected to perform as well as reformulated OxyContin when subjected to manipulations by individuals intent on abusing the product or by patients/caregivers inadvertently misusing the medication, was received by this office on 10/22/2013. It was assigned docket number FDA-2013-P-1375/CP1, and it was filed on 11/15/2013. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)