



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 18, 2013

FILE COPY

Patricia A. Fritz
VP, Corporate Affairs & Operations
UCB, Inc.
1950 Lake Park Drive
Smyrna, GA 30080

Dear Ms. Fritz:

Your petition to the Food and Drug Administration requesting the Agency to determine that the NCE exclusivity for lacosamide began on June 9, 2009, and thus will end on June 9, 2014; and confirm that the Agency will stay approval of ANDAs Nos. 204682, 204787, 204839, 204857, 204873, 204874, 204855, 204921, 204947, 204974, 204980, 204986, 204994, 204999, 205006, 205011, 205026, 205031, 205237 until December 7, 2016, was received by this office on 10/28/2013. It was assigned docket number FDA-2013-P-1397/CP1, and it was filed on 11/18/2013. 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
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)