



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

October 25, 2013

Timothy P. Walbert  
Chairman, President and Chief Executive Officer  
Horizon Pharma, Inc.  
520 Lake Cook Rd, Suite 520  
Deerfield, IL. 60015

Dear Mr. Walbert:

Your petition to the Food and Drug Administration requesting the Agency to establish bioequivalence for any ANDA that lists RAYOS tablets as the RLD, was received by this office on 10/17/2013. It was assigned docket number FDA-2013-P-1283/CP1, and it was filed on 10/25/2013. 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,

A handwritten signature in black ink, reading "Karen Kennard", is written above the typed name.

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