DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

September 16, 2013

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

Dear Mr. Walbert:

Your petition to the Food and Drug Administration with respect to any Abbreviated New Drug Application ("ANDA") submitted to FDA and listing RAYOS® (prednisone) delayed-release tablets 1 mg, 2 mg, or 5 mg ("RAYOS® tablets") as the reference listed drug ("RLD"), was received by this office on 09/04/2013. It was assigned docket number FDA-2013-P-1082/CP1, and it was filed on 09/04/2013. 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)

FDA-2013-P-1082

ACK