



October 4, 2013

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BY COURIER

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, Maryland 20852

**RE: Citizen Petition 2013- P-1082
Bioequivalence for ANDAs Referencing NDA No. 202020 for RAYOS[®]
(prednisone) Delayed-Release Tablets**

Dear Sir or Madam:

Reference is made to a phone conversation with Ms. Nicole Mueller on October 1, 2013 regarding the above mentioned Citizen Petition originally submitted to the Agency on September 3, 2013. Ms. Mueller indicated that the language provided in Section V Certifications was not congruent with the language outlined in Guidance for Industry, Citizen Petitions and Petitions for Stay of Action Subject to Section 510(q) of the Federal Food, Drug and Cosmetic Act, dated June 2011.

Horizon is, therefore, respectfully withdrawing Citizen Petition 2013-P-1082 with the intention of resubmitting the petition with the modified Section V language in accordance with the guidance document.

Sincerely,

A handwritten signature in black ink, appearing to read 'Timothy P. Walbert'.

Timothy P. Walbert
Chairman, President and Chief Executive Officer

224.383.3009 – o
847.572.1372 – f
twalbert@horizonpharma.com

UPS CampusShip: View/Print Label

1. **Ensure there are no other shipping or tracking labels attached to your package.** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.
2. **Fold the printed sheet containing the label at the line so that the entire shipping label is visible. Place the label on a single side of the package and cover it completely with clear plastic shipping tape. Do not cover any seams or closures on the package with the label.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

3. **GETTING YOUR SHIPMENT TO UPS**

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Schedule a same day or future day Pickup to have a UPS driver pickup all your CampusShip packages.

Hand the package to any UPS driver in your area.

Take your package to any location of The UPS Store®, UPS Drop Box, UPS Customer Center, UPS Alliances (Office Depot® or Staples®) or Authorized Shipping Outlet near you. Items sent via UPS Return Services(SM) (including via Ground) are also accepted at Drop Boxes. To find the location nearest you, please visit the Resources area of CampusShip and select UPS Locations.

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Your driver will pickup your shipment(s) as usual.

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BILLING: P/P		Department Number: 30 Reference # 2: WD Citizen Petition CS 15.6.12. WNTIE90 42.0A 07/2013	