VALEANT
Pharmaceuticals North America LLC

Valeant Pharmaceuticals North America LLC
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Via Electronic Submissions Gateway

June 21, 2013

Debra Birnkrant, M.D., Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antiviral Products
Attention: ELECTRONIC DOCUMENT ROOM
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: **NDA 22-436 Xerese® (acyclovir and hydrocortisone) Cream 5%/1%**
Response to PREA Non-Compliance Letter
Deferral Extension Requested
Sequence Number: 0059

Dear Dr. Birnkrant:

Reference is made to the Valeant International Bermuda (Valeant) NDA 22-436 for Xerese (acyclovir and hydrocortisone) Cream 5%/1% approved on July 31, 2009. Further reference is made to the pediatric assessment (consisting of the final clinical study report for pediatric study MP800), which Valeant submitted to this NDA on April 23, 2013, and to your letter titled "Notification of Non-Compliance with PREA" (Pediatric Research Equity Act), dated May 07, 2013.

In your letter, you stated that the Agency has determined that Valeant failed to meet the requirements of the PREA because Valeant has not submitted its pediatric assessment for Xerese, which was deferred until May 01, 2013. As noted above, Valeant did submit the final clinical study report for pediatric study MP800 to the NDA on April 23, 2013 – more than a week in advance of the end of the deferral period for the pediatric assessment. However, due to the lack of clarity regarding certain administrative aspects of complying with recently enacted provisions of the Food and Drug Administration Safety and Innovation Act (FDASIA),[1] Valeant submitted the final report for study MP800 as general correspondence to the NDA on April 23, 2013. After discussions with members of the Division, the company now understands that the Agency's expectation is that a clinical study report required under PREA should be submitted as a formal supplement to the NDA.

[1] FDASIA was signed into law on July 9, 2012. Relevant pediatric provisions of the law went into effect 270 days after July 09, 2012, which was April 08, 2013. 21 USC 355c(d)(1).

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Although Valeant believes that it has already fully complied with its obligations under PREA through the submission of the MP800 study report on April 23, 2013, the company will re-submit the study report in a supplement to the Xerese NDA as you requested. Following recent discussions with Victoria Tyson of the Antiviral Division, Valeant is requesting a deferral extension to July 31, 2013, when the requested NDA supplement with the pediatric assessment would be submitted.

We are providing this information on behalf of Valeant International Bermuda. Please contact me at 908-927-1706, or by email at Steven.Knapp@valeant.com if you have any questions about the information contained in this letter.

Sincerely,

Steven J. Knapp, MS, PharmD
Vice President, Regulatory Affairs

cc: -John B. Dubeck, US Agent for Valeant International Bermuda
-Medivir AB, Sponsor of IND (b) (4)
-Pediatric and Maternal Health Staff, Office of New Drugs, CDER

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Program Version	10.0 Service Pack 1
Scan Engine Version	9.700.1001
Virus Definition Date	06/20/2013
Submission Size	Approximately 1 MB

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