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# OxyHealth, LLC - Close Out Letter 4/8/14



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

APR 08, 2014

Samir Patel  
President  
OxyHealth, LLC  
10719 Norwalk Blvd.  
Santa Fe Springs, California 90670

Dear Mr. Patel:

The Food and Drug Administration has completed an evaluation of your corrective actions in response to our Warning Letter # 406207 dated August 8, 2013. Based on our evaluation, it appears that you have addressed the violations contained in this Warning Letter. Future FDA investigations and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

/S/

William C. MacFarland  
Director  
Division of Manufacturing and Quality  
Office of Compliance  
Center for Devices and Radiological Health

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