DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

November 13, 2013

David B. Redwine
2190 NE Professional Court
Bend, Oregon 97701

Dear Dr. Redwine,

I would like to thank you for your correspondence with FDA and your review entitled *Leuprolide—The "D" is Silent*, dated October 2011. FDA welcomes this information and any such relevant data as they become available.

We have completed an extensive and careful review of your submission and have concluded that the information and analyses you provided do not change our risk–benefit assessment for Lupron Depot for the treatment of endometriosis. In addition, we have concluded that the current labeling for Lupron Depot is adequate from efficacy and safety perspectives. Therefore, we have determined that no regulatory action is needed for Lupron Depot at this time.

We continue to monitor adverse events for Lupron Depot, as we have done since its approval and as we do for all FDA-approved medications.

Thank you again for contacting us with your concerns.

Sincerely,

Michelle Eby

Michelle Eby, Pharm.D.
Consumer Safety Officer
Office of Executive Programs
Center for Drug Evaluation and Research