DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

8/21/14

Joan Janulis
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Ave.
Westbury, NY 11590

Re: Docket No. FDA-2013-P-1510

Dear Ms. Janulis:

This letter responds to your citizen petition dated November 5, 2013, requesting that the Food and Drug Administration (FDA) determine whether Lupron Depot-Ped, Injectable 3.75 milligrams (mg)/vial and 7.5 mg/vial (leuprolide acetate for depot suspension) (New Drug Application (NDA) 020263) and Lupron Depot-Ped, Injectable 7.5 mg/vial and 7.5 mg/vial (NDA 020263), were voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that Lupron Depot-Ped, Injectable 3.75 milligrams/vial and 7.5 mg/vial and Lupron Depot-Ped, Injectable 7.5 mg/vial and 7.5 mg/vial were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain these products, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-0979.

Sincerely,

Daniel E. Orr
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure