DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY 0 2 2014

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

Re: FDA-2013-P-1510

Dear Ms. Janulis:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on November 5, 2013. Your petition requests that FDA determine whether the drug products Lupron Depot-Ped, Injectable 3.75 milligrams/Vial and 7.5 mg/Vial (leuprolide acetate for depot suspension) (New Drug Application 020263) and Lupron Depot-Ped, Injectable 7.5 mg/Vial and 7.5 mg/Vial (NDA 020263) have been voluntarily withdrawn from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research