DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY 0 2 2014

Terri Nataline
Principal Consultant
Lachman Consultant Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590

Re: FDA-2013-P-1609

Dear Ms. Nataline:

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 26, 2013. Your petition requests that FDA determine whether the two-vial closure system that was previously used to package certain Lupron Depot (leuprolide acetate for depot suspension) injection drug products was voluntarily withdrawn for safety or efficacy reasons.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