DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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December 2, 2013

Joan Janulis, R.A.C.
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Dear Ms. Janulis:

Your petition to the Food and Drug Administration requesting the Agency to determine whether the drug products Lupron Depot-Ped, Injectable, 3.75 mg/Vial and 7.5 mg/Vial (leuprolide acetate for depot suspension) (NDA 020263, product No. 003) and Lupron Depot-Ped, Injectable, 7.5 mg/Vial and 7.5 mg/Vial (NDA 020263. Product No. 004) have been voluntarily withdrawn from sale for safety or efficacy reasons, was received by this office on 11/5/2013. It was assigned docket number FDA-2013-P-1510/CP1, and it was filed on 12/2/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)