DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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December 12, 2013

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

Dear Ms. Nataline:

Your petition to the Food and Drug Administration requesting the Agency to determine whether the two-vial container closure system that was previously used to package the following Lupron Depot (leuprolide acetate for depot suspension) injection drug products was voluntarily withdrawn from sale for safety or efficacy, was received by this office on 11/26/2013. It was assigned docket number FDA-2013-P-1609/CP1, and it was filed on 12/12/2013. 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)