DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration Silver Spring MD 20993

Dear Ms. Millican:

Thank you for your letter of September 17, 2009, to the Food and Drug Administration regarding your request that the FDA investigate the drug Lupron Depot (leuprolide acetate) and have it removed from the market. Your letter was forwarded to the Center for Drug Evaluation and Research to respond. We are sorry to hear about the problems you and others have encountered while using this drug.

All drug products contain risks as well as benefits, and it is often impossible to predict which individuals may have increased sensitivity to particular drugs. Before approving a drug, FDA takes into account the known risks associated with a drug along with the benefits the drug will provide. FDA realizes that when an approved new drug becomes widely used in clinical practice, health care professionals may observe differences from clinical trial results in both the incidence and/or types of adverse drug experiences. FDA is committed to following post-marketing adverse events and taking the necessary regulatory actions to communicate new information about drugs after approval.

The Agency monitors the safety of drug products, including the incidence and severity of adverse reactions, through its voluntary MedWatch program and pharmaceutical companies' annual and periodic safety reports. FDA relies on these submissions and reports to help detect problems with drug products once they are on the market.

The information received about an adverse drug experience is added to the existing data in our Adverse Event Reporting System (AERS) database. The collected reports are monitored and observed for emerging patterns. In the event it appears there may be a potential for a widespread product problem, the Agency will initiate action as needed. We have forwarded your concern and information to the appropriate CDER division to consider in the context of other information from our AERS database.

Thank you for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

Candra Smith
Consumer Safety Officer
Division of Executive Operations
Center for Drug Evaluation and Research