LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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OVERNIGHT DELIVERY 11/4/13

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20552

CITIZEN PETITION

Dear Sir or Madam:

Lachman Consultant Services, Inc. (Lachman) is submitting this Citizen Petition in quadruplicate pursuant to 21 § C.F.R. 10.30 and in accordance with the regulations of 21 § C.F.R. 314.161, on behalf of a client, to request that the Commissioner of the Food and Drug Administration determine whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration 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020263, Product No. 004) (hereafter, collectively, the "Lupron Depot-Ped" dual vial products) have been voluntarily withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book"). The Lupron Depot-Ped dual-vial products are currently listed in the Discontinued Section of the electronic Orange Book on FDA's website. According to the Preface to the Orange Book,[1] a drug product in the Discontinued Section as to which a determination has already been made that withdrawal was not for safety or effectiveness reasons will include the following statement after its product strength: "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons." There is no such annotation for Lupron Depot-Ped. See **Attachment 1**. The petitioner asks the FDA to determine that the NDA holder, Abbvie Endocrine, Inc. (formerly Abbott Endocrine) ("Abbvie"), voluntarily withdrew the two identified packaging configurations of Lupron Depot-Ped from sale for reasons other than safety or effectiveness.

Abbvie originally received FDA approval for Lupron Depot-Ped in April 1993, in a packaging configuration that included the active ingredient (leuprolide acetate) as sterile lyophilized microspheres in one vial, and a diluent for reconstitution in a second vial or ampule. FDA approved a different packaging configuration

[1] Available at http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm.

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on October 26, 1995 (NDA 020263, S-006) for a pre-filled dual-chamber syringe filled with both leuprolide acetate and the diluent. After that approval, Abbvie discontinued the single-dose vial-and-ampule version (the "dual-vial" products). The petitioner believes that the sale of these drug products in a single-dose vial with an accompanying ampule was discontinued in 1998. Today, Abbvie continues to sell the active ingredient of Lupron Depot-Ped in other packaging configurations and strengths – consider NDA 020263, Product Nos. 002, 005, 006, 007, and 008.

After a review of publicly available information, including searches on the Internet using common search engines, such as Google and Yahoo, it appears that Abbvie did not withdraw the dual vial versions of Lupron Depot-Ped for safety or effectiveness reasons. In particular, we note the following research results:

- Trade press searches did not reveal information suggesting that the dual-vial versions of Lupron Depot-Ped were withdrawn for safety or effectiveness reasons. Specifically, there were no trade press articles discussing Abbvie's decision to discontinue the sale of these drug products with the combination vial/ampule delivery mechanism.

- There are no published state or federal court decisions relating to product liability arising out of the use of the Lupron Depot-Ped's dual-vial delivery mechanism.

Under FDA regulations, drugs are withdrawn from the market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 C.F.R. § 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 § C.F.R. 314.161(a)(1)).

The available information suggests that the dual-vial Lupron Depot-Ped products were not withdrawn for safety or effectiveness reasons. Rather, it appears that Abbvie withdrew Lupron Depot-Ped for voluntary reasons unrelated to the product's safety or effectiveness. The Petitioner, therefore, requests that the FDA determine that Abbvie's voluntary withdrawal of Lupron Depot-Ped from sale was for reasons other than safety or effectiveness in order to enable action on an ANDA referring to Lupron Depot-Ped product as the Reference Listed Drug. It also requests that the Agency publish a notice of its determination in the *Federal Register* and to appropriately annotate the Orange Book.

Should the NDA holder recommence marketing its Lupron Depot-Ped products after the submission of this petition and prior to an FDA response, and there is evidence that the product is available in the marketplace, the petitioner will consider this petition moot. The petitioner will at that time take the appropriate action to request withdrawal of the petition.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

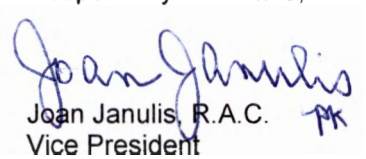
D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which is unfavorable to the petition.

Respectfully submitted,



Joan Janulis, R.A.C.
Vice President

JJ/pk

Attachment: Discontinued Section of Orange Book accessed 10/31/2013

cc: Martin Shimer (Office of Generic Drugs)

Petition Lupron Depot-Ped 110413 (40156)

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