4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-P-1510]

Determination That LUPRON DEPOT-PED (Leuprolide Acetate for Depot Suspension), Injectable 3.75 Milligrams/Vial and 7.5 Milligrams/Vial; and LUPRON DEPOT-PED (Leuprolide Acetate for Depot Suspension), Injectable 7.5 Milligrams/Vial and 7.5 Milligrams/Vial, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 3.75 milligrams (mg)/vial and 7.5 mg/vial; and LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for leuprolide acetate for depot suspension, injectable 3.75 mg/vial and 7.5 mg/vial; and injectable 7.5 mg/vial and 7.5 mg/vial, if all other legal and regulatory requirements are met. However, in considering whether to file an ANDA for leuprolide acetate for depot suspension, future applicants are advised that they may not be able to obtain LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, for bioequivalence testing because the product has not been commercially available for a number of years. An ANDA applicant who is unable to obtain LUPRON DEPOT-PED (leuprolide acetate

for depot suspension), Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, for bioequivalence testing should contact the Office of Generic Drugs for a determination of what is necessary to show bioavailability and the same therapeutic effect.

FOR FURTHER INFORMATION CONTACT: Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6208, Silver Spring, MD 20993-0002, 240-402-0979.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, are the subject of NDA 020263, held by Abbvie Endocrine, Inc., and initially approved on April 16, 1993. LUPRON DEPOT-PED is indicated for treatment of children with central precocious puberty.

In a report dated January 30, 1999, Abbvie notified FDA that LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT-PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, were being discontinued, and FDA moved the drug products to the "Discontinued Drug Product List" section of the Orange Book.

Joan Janulis, on behalf of Lachmann Consultant Services, Inc., submitted a citizen petition dated November 4, 2013 (Docket No. FDA-2013-P-1510), under 21 CFR 10.30, requesting that the Agency determine whether LUPRON DEPOT-PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT-PED, Injectable 7.5 mg/vial and 7.5 mg/vial, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LUPRON DEPOT-PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT-PED, Injectable 7.5

mg/vial and 7.5 mg/vial, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LUPRON DEPOT-PED, Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT-PED, Injectable 7.5 mg/vial and 7.5 mg/vial, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LUPRON DEPOT-PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT-PED, Injectable 7.5 mg/vial and 7.5 mg/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LUPRON DEPOT-PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT-PED, Injectable 7.5 mg/vial and 7.5 mg/vial, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to LUPRON DEPOT-PED, Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT-PED, Injectable 7.5 mg/vial and 7.5 mg/vial, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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