DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–1609]

Determination That LUPRON DEPOT (Leuprolide Acetate for Depot Suspension), Injectable 3.75 Milligrams/Vial Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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determined that LUPRON DEPOT (leuprolide acetate for depot suspension), Injectable 3.75 milligrams (mg)/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for LUPRON DEPOT (leuprolide acetate for depot suspension), Injectable 3.75 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 (leuprolide acetate for depot suspension), Injectable 3.75 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 (leuprolide acetate for depot suspension), Injectable 3.75 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 (Pub. L. 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). FDA may not approve an ANDA that does not refer to a listed drug.

LUPRON DEPOT (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial, is the subject of NDA2001, held by Abbvie Endocrine, Inc. (Abbvie), and initially approved on October 22, 1990. LUPRON DEPOT is indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. LUPRON DEPOT, concomitantly with iron therapy, is also indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata.

In a report dated December 15, 1999, Abbvie notified FDA that LUPRON DEPOT (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Terri Nataline, on behalf of Lachman Consultant Services, Inc., submitted a citizen petition dated November 25, 2013 (Docket No. FDA–2013–P–1609), under 21 CFR 10.30, requesting, in part, that the Agency determine whether LUPRON DEPOT, Injectable 3.75 mg/vial, was 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, Injectable 3.75 mg/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LUPRON DEPOT, Injectable 3.75 mg/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LUPRON DEPOT, Injectable 3.75 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, Injectable 3.75 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, Injectable 3.75 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: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1439]

Critical Path Innovation Meetings; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Critical Path Innovation Meetings.'' This draft guidance describes a Critical Path Innovation Meeting (CPIM), a means by which FDA's Center for Drug Evaluation and Research (CDER) and investigators