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Determination That LUPRON DEPOT (Leuprolide Acetate for Depot Suspension), Injectable 3.75 Milligrams/Vial Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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determined that LUPRON DEPOT (leuprolide acetate for depot suspension), Injectable 3.75 milligrams (mg)/vial, was not withdrawn from sale for reasons of safety or effectiveness.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

from industry, academia, government, and patient advocacy groups can communicate to improve efficiency and success in drug development. The goals of the CPIM are to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how this methodology or technology might enhance drug development. The discussions and background information submitted through the CPIM are nonbinding on both FDA and CPIM requesters.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 8, 2014.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Alicia Stuart, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4547, Silver Spring, MD 20993–0002, 301–796–3852.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Critical Path Innovation Meetings.'' The draft guidance describes the purpose and scope of a CPIM and how to request such a meeting. A CPIM provides the opportunity to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how the methodology or technology might enhance drug development. During a CPIM, CDER will identify some of the larger gaps in existing knowledge that requesters might consider addressing in the course of their work. The discussions and background information submitted through the CPIM are nonbinding on both FDA and CPIM requesters. The CPIM initiative meets Prescription Drug User Fee Act (PDUFA) V Reauthorization Goal IX.A, ''Enhancing Regulatory Science and Expediting Drug Development'' by ''Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development.''

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on CPIMs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910–0014. The collection of information in 21 CFR part 314 (new drug applications) has been approved under OMB control number 0910–0001. The collection of information resulting from formal meetings between interested persons and FDA has been approved under OMB control number 0910–0429.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 2, 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–1411]

The Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards: Questions and Answers; 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 ''The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers.'' FDA is issuing these questions and answers to assist industry and State governments in understanding the effects of section 585 (Uniform National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) added by Title II of the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013, on State product tracing requirements and on standards, requirements, and regulations with respect to wholesale distributor and third-party logistics provider (3PL) licensing. Title II is also referred to as the Drug Supply Chain Security Act (DSCSA).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 8, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New