DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–P–1896]

Determination That OXYTOCIN in 5% Dextrose Injection Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 or Agency) has determined that OXYTOCIN 5 United States Pharmacopeia (USP) Units in Dextrose 5% (oxytocin), injectable, injection, 5 USP Units in 500 milliliters (mL), (1 USP Unit/100 mL); OXYTOCIN 10 USP Units in Dextrose 5% (oxytocin), injectable, injection, 10 USP Units in 500 mL, (2 USP Units/100 mL); OXYTOCIN 10 USP Units in Dextrose 5% (oxytocin), injectable, injection, 10 USP Units in 1000 mL, (1 USP Unit/100 mL); and OXYTOCIN 20 USP Units in Dextrose 5% (oxytocin), injectable, injection, 20 USP Units in 1000 mL, (2 USP Units/100 mL), (hereinafter ''these oxytocin drug products'') were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve an abbreviated new drug application (ANDA) for these oxytocin drug products, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Robin Fastenau, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 240–402–4510.

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 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

These oxytocin drug products are the subject of NDA 019–185, held by Abbott Laboratories, and initially approved on March 29, 1985. These oxytocin drug products are indicated for the initiation or improvement of uterine contractions. In a December 26, 1995, letter, Abbott Laboratories notified FDA that these oxytocin drug products were being discontinued and requested withdrawal of NDA 019–185. In the **Federal Register** of March 27, 1996 (61 FR 13506), FDA announced that it was withdrawing approval of NDA 019–185, effective April 26, 1996. FDA has moved these oxytocin drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

TechReg Services, Inc. (TechReg), submitted a citizen petition dated November 12, 2014 (Docket No. FDA–2014–P–1896), under 21 CFR 10.30, requesting that the Agency determine whether Oxytocin in Dextrose 5%, injection, available as strengths 5, 10, and 20 units under Abbott NDA 019–185, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not specify the concentrations of the three strengths associated with NDA 019–185, we have considered whether any of these oxytocin drug products approved under NDA 019–185 were withdrawn for safety or effectiveness reasons.

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 these oxytocin drug products were not withdrawn for reasons of safety or effectiveness. TechReg has identified no data or other information suggesting that these oxytocin drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of these oxytocin drug products from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these oxytocin drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list these oxytocin drug products 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 these oxytocin drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. FDA has determined that labeling for these oxytocin drug products should be revised to meet current standards and will advise ANDA applicants how to submit such labeling.

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1163]

Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs, 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 ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' This draft guidance explains how manufacturers, packers, and distributors (firms) that may either be the applicant or acting on