

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-P-0528]

Determination That CITANEST (Prilocaine Hydrochloride) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (Prilocaine Hydrochloride) Injection, 4%, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 CITANEST (prilocaine hydrochloride (HCl)) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for prilocaine HCl injection, 1%, 2%, and 3%, and prilocaine HCl injection, 4%, if all legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: S. Mitchell Weitzman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6318, Silver Spring, MD 20993-0002, 301-796-3511.

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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, are the subject of NDA 14-763, held by AstraZeneca, and initially approved on November 18, 1965. CITANEST and CITANEST PLAIN are indicated for the production of local anesthesia in infiltration procedures, peripheral nerve blocks, and epidural or caudal blocks.

In a letter dated August 28, 2002, AstraZeneca notified FDA that they had decided to withdraw NDA 14-763 for CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%; CITANEST PLAIN (prilocaine HCl) Injection, 4%; and CITANEST FORTE (epinephrine bitartrate and prilocaine HCl) Injection, 0.005 milligrams/milliliter and 4%,¹ in accordance with 21 CFR 314.150(c). FDA moved the drug products to the "Discontinued Drug Product List" section of the Orange Book. In the **Federal Register** of August 18, 2003 (68 FR 49481), FDA announced that it was withdrawing approval of NDA 14-763, effective September 17, 2003.

Lachman Consultant Services, Inc., submitted a citizen petition dated September 25, 2008 (Docket No. FDA-2008-P-0528), under 21 CFR 10.30, requesting that the Agency determine whether prilocaine HCl injections, 1%, 2%, 3%, and 4%, NDA 14-763, 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 CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl)

¹ This notice does not include a determination as to whether CITANEST FORTE, approved under NDA 14-763, was withdrawn from sale for reasons of safety or efficacy.

Injection, 4%, were not withdrawn for reasons of safety or effectiveness.

The petitioner has identified no data or other information suggesting that CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, 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 CITANEST (prilocaine HCl) Injections, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, 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 CITANEST (prilocaine HCl) Injection, 1%, 2%, and 3%, and CITANEST PLAIN (prilocaine HCl) Injection, 4%, 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: March 13, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0226]

Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program; Availability

AGENCY: Food and Drug Administration, HHS.