

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-P-0604]

Determination That PITRESSIN TANNATE IN OIL (Vasopressin Tannate) Injection, 5 Pressor Units/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.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has determined that PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for vasopressin tannate injection, 5 pressor units/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6246, Silver Spring, MD 20993-0002, 301-796-3543.

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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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 (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/mL, is the subject of NDA 03-402, held by Parke-Davis Pharmaceutical Research (Parke-Davis). PITRESSIN TANNATE IN OIL is indicated for the control or prevention of the symptoms and complications of diabetes insipidus due to a deficiency of endogenous posterior pituitary antidiuretic hormone.

In a letter dated April 23, 1993, Parke-Davis requested the withdrawal of NDA 03-402 for PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/mL. In the **Federal Register** of September 25, 1998 (63 FR 51359), FDA announced that it was withdrawing approval of NDA 03-402, effective September 25, 1998.

Lachman Consultant Services, Inc., submitted a citizen petition dated November 19, 2010 (Docket No. FDA-2010-P-0604), under 21 CFR 10.30, requesting that the Agency determine whether PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/mL, 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 PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/mL, 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 this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/mL, 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 PITRESSIN TANNATE IN OIL (vasopressin tannate) Injection, 5 pressor units/mL, 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 14, 2012.

Leslie Kux,*Assistant Commissioner for Policy.*

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[Docket No. FDA-2009-D-0573]

International Conference on Harmonisation; Addendum to International Conference on Harmonisation Guidance on S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals; Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "S6 Addendum to Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals" (S6 addendum). The S6 addendum was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The S6 addendum is intended to incorporate new knowledge and experience gained since the implementation of the ICH guidance