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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2003P–0393]

Determination That DIAZEPAM Injection United States Pharmacopeia (5 Milligrams/Milliliter in a 1-Milliliter Container) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that DIAZEPAM Injection United States Pharmacopeia (USP) (5 milligrams/milliliter (mg/mL) in a 1-mL container) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for DIAZEPAM Injection USP (5 mg/mL in a 1-mL container).

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors 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 typically a version of the drug that was

previously approved. Sponsors of ANDAs 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 generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness §314.162 (21 CFR 314.162).

Under § 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) is the subject of approved ANDA 72–079 held by Abbott Laboratories, Inc. (Abbott). DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety. PharmaForce, Inc., submitted a citizen petition dated August 25, 2003 (Docket No. 2003P–0393/CP1), under 21 CFR 10.30, requesting that the agency determine whether DIAZEPAM Injection USP (5 mg/mL, 1 mL) was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that DIAZEPAM Injection USP in a 5-mg strength (5 mg/mL in a 1–mL container) was not withdrawn from sale for reasons of safety or effectiveness. Two grounds support the agency's finding. First, DIAZEPAM Injection USP currently is being marketed in a 10-mg strength (5 mg/mL in a 2-mL container). Adverse drug events would be less likely with the discontinued lower dose than the currently marketed higher dose. In addition, by using only a portion of the amount currently marketed, the 5-mg strength in question still can be obtained. Second, the lower 5-mg strength of DIAZEPAM Injection USP would be considered an effective dosage form because it is still within the dosing range. The usual recommended dose for older children and adults ranges from 2 to 20 mg intramuscularly or intraveneously, depending on the indication and its severity.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, DIAZEPAM Injection, USP (5 mg/mL in a 1-mL container) was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) 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 DIAZEPAM Injection USP (5 mg/mL, 1 mL) may be approved by the agency.

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Dated: 3/8/04

March 8, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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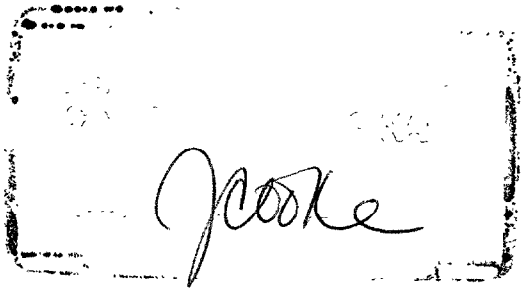
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