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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0445]

Determination That MIVACRON (Mivacurium Chloride) Injection Equivalent to 2 Milligrams Base/Milliliter Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that MIVACRON (mivacurium chloride) injection equivalent to (EQ) 2 milligrams (mg) base/milliliter (mL) was not withdrawn from sale for reasons of safety or effectiveness.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 mivacurium chloride injection EQ 2 mg base/mL.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, 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 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

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of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 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.

MIVACRON (mivacurium chloride) injection EQ 2 mg base/mL is the subject of approved NDA 20–098 held by Abbott Laboratories, Inc. (Abbott). MIVACRON is a short-acting neuromuscular blocking agent indicated for inpatients and outpatients, as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. FDA approved the NDA for MIVACRON on January 22, 1992. Abbott ceased marketing MIVACRON in July 2006.

Regulus Pharmaceutical Consulting, Inc., submitted a citizen petition dated October 25, 2006 (Docket No. 2006P–0445/CP1), under 21 CFR 10.30,

requesting that the agency determine, as described in § 314.161, whether MIVACRON (mivacurium chloride) injection EQ 2 mg base/mL was withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MIVACRON was withdrawn from sale as a result of safety or effectiveness concerns.

We have reviewed our records and determined that Abbott's MIVACRON (mivacurium chloride) injection EQ 2 mg base/mL was not withdrawn from sale for reasons of safety or effectiveness. We have also independently evaluated relevant literature and data for adverse event reports and have determined that this product was not withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA has determined that, for the reasons outlined in this notice, Abbott's MIVACRON (mivacurium chloride) injection EQ 2 mg base/mL was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will list MIVACRON (mivacurium chloride) injection EQ 2 mg base/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 MIVACRON (mivacurium chloride) injection EQ 2 mg base/mL may be approved by the agency as long as they meet all relevant 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: 7/30/07
July 30, 2007.

Randall W. Luther,
Deputy Commissioner for Policy.

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