Agreement to the National Alliance for Hispanic Health (the Alliance). The purpose of the agreement is to empower consumers to improve their health by providing better consumer health information; ensure that health information available to consumers is clear, informative, and effective; leverage opportunities to eliminate health disparities in subpopulations; respond to the health promotion and disease prevention objectives of the Department of Health and Human Services (HHS) ''Healthy People 2010'' document; and improve health literacy for Hispanic Americans. FDA anticipates providing $ 35,000.00 (direct and indirect costs) in fiscal year (FY) 2007 in support of this project. Subject to the availability of funds and successful performance, two additional years of support up to $35,000.00 per year (direct and indirect) will be available.

DATES: Applications are due August 24, 2007.

FOR FURTHER INFORMATION CONTACT: Gladys M. Bohler, Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301–827–7168, or e-mail: *gladys.melendez-bohler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Application and Submission Information

In FY 2007, all applications must be received by August 24, 2007. Applications must be received by close of business on the established receipt date. Late applications may be accepted under extreme circumstances beyond the control of the applicant. Applicants not received on time will not be considered for review and will generally be returned to the applicant.

Applications must be submitted electronically through grants.gov. The application must be on SF424 R&R (Research and Related Portable Document Format). Exceptions may be made in unusual circumstances and on a case by case basis. Applicants must download the SF424 (R&R) application forms and 424 (R&R) Application Guide for this funding opportunity through grants.gov at *http://www.grants.gov/Apply*. Please note, only the forms package directly attached to this specific funding opportunity in grants.gov can be used.

If electronic submission is impossible, please contact Gladys M. Bohler, Grants Management Specialist, at 301–827–7168 or by e-mail at *gladys.melendez-bohler@fda.hhs.gov* (See **Agency Contacts**). When submitting applications electronically, provide URL link, and identify any particular software that is required, and identify your organization contact in the event of system problems.

For the grants.gov electronic application process, applicants are required to register with the Central Contractor Registration (CCR) database. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government.

Registration with CCR is a requirement and is consistent with the government-wide management reform to create a citizen-centered Web presence and build e-gov infrastructures in and across agencies to establish a ''single face to industry.'' The preferred method for completing a registration is through the World Wide Web at *http://www.ccr.gov*. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online registration, as well as steps to walk you through the registration process.

In order to access grants.gov, an applicant will be required to register with the Credential Provider. Information about this is available at *https://apply.grants.gov/OrcRegister.* (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

II. Agency Contacts

For issues regarding the administrative and financial management aspects of this notice, contact: Gladys M. Bohler by mail: Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857; telephone: 301–827–7168; FAX: 301–827–7101; e-mail: *gladys.melendez-bohler@fda.gov*.

For issues regarding the programmatic aspects, contact: Mary C. Hitch, Senior Policy Advisor, Office of External Relations (HF–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; telephone: 301–827–4406; FAX: 301–827–8030; e-mail: *mary.hitch@fda.hhs.gov*.

Dated: August 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–15491 Filed 8–7–07; 8:45 am]

BILLING CODE 4160–01–S

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 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: July 30, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15488 Filed 8–7–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0520]

Determination That Methotrexate Injection, USP, Preservative Free, Equivalent to 500 Milligrams Base/20 Milliliters (25 Milligrams/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 methotrexate injection, USP, preservative free, equivalent to (Eq.) 500 milligrams (mg) base/20 milliliters (mL) (25 mg/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 methotrexate injection, preservative free, Eq. 500 mg base/20 mL (25 mg/mL).

FOR FURTHER INFORMATION CONTACT: Elena Cohen, 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 typically 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 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 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.

Methotrexate injection, USP, preservative free, Eq. 500 mg base/20 mL (25 mg/mL), is the subject of approved NDA 11–719 currently held by Mayne Pharma USA (Mayne). Although NDA 11–719 was originally approved in 1959, this formulation and dosage was approved in April 2005 (S–108). Methotrexate is an antifolate cytotoxic drug used in the treatment of a variety of malignancies, including acute lymphoblastic leukemia, osteosarcoma, advanced metastatic breast cancer, and others. It is also used to treat some inflammatory conditions such as rheumatoid arthritis. To date, Mayne has not marketed methotrexate injection, USP, preservative free, Eq. 500 mg base/20 mL (25 mg/mL). At the request of the sponsor, the product was moved to the discontinued section of the Orange Book in June 2005. In previous instances (see, e.g., the **Federal Register** document of December 30, 2002 (67 FR 79640), addressing a relisting request for Diazepam Autoinjector), the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

SICOR Pharmaceuticals, Inc., submitted a citizen petition dated