



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-871

Food and Drug Administration  
Rockville MD 20857

APR 11 2006

Mayne Pharma (USA) Inc.  
Attention: Germaine Matti  
Regulatory Affairs Associate  
Mack-Cali Centre II, Second floor  
650 From Road  
Paramus, NJ 07652

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 16, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Mitoxantrone Injection USP, (Concentrate), 2 mg/mL, packaged in 20 mg/10 mL, 25 mg/12.5 mL, and 30 mg/15 mL Multiple-dose vials.

Reference is also made to the Tentative Approval letter issued by this office on July 23, 2004, and to your amendments dated September 9, and December 16, 2005; and January 6, January 25, February 2, February 24, and March 2, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Mitoxantrone Injection USP, (Concentrate), 2 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Novantrone Injection (Concentrate), 2 mg/mL, of Serono, Inc.).

The reference listed drug product (RLD) referenced in your application, Novantrone Injection (Concentrate), 2 mg/mL, of Serono, Inc. has been subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book" U.S. Patent No. 4,617,319 (the '319 patent) expired on June 13, 2005, and U.S. Patent No. 4,820,738 (the '738 patent) expired on April 11, 2006.

Your ANDA contains paragraph III certifications to each of the listed patents under section 505(j)(2)(A)(vii)(III) of the Act. These certifications state that Mayne Pharma (USA) Inc. will not market Mitoxantrone Injection USP, (Concentrate), 2 mg/mL, under this ANDA prior to the expiration of both of the listed patents. Since each patent has expired, the agency is no longer precluded from approving your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,



Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research