DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-410

Osmotica Pharmaceutical Corp.
Attention: Mark S. Aikman, Pharm.D.
Vice President, Regulatory Affairs and QA
1205 Culbreth Drive, Suite 200
Wilmington, NC 28405

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 19, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Nifedipine Extended-release Tablets USP, 90 mg.

Reference is made to the tentative approval letter issued by this office on December 28, 2006, and to your amendments dated November 22, 2005; March 17, August 4, October 20, and November 30, 2006; and September 20, September 25, and September 28, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Nifedipine Extended-release Tablets USP, 90 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Procardia XL Tablets, 90 mg, of Pfizer Laboratories (Pfizer).

The reference listed drug (RLD) upon which you have based your ANDA, Pfizer's Procardia XL Tablets, is 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. 5,264,446 (the '446 patent), is scheduled to expire on November 23, 2010.

Your ANDA contains a paragraph IV certification to the '446 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Nifedipine Extended-release Tablets USP, 90 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Osmotica Pharmaceutical Corp. (Osmotica) for infringement of the '466 patent. You have notified the agency that Osmotica complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Osmotica within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

Furthermore, the 180-day generic drug exclusivity issue noted in our tentative approval letter dated December 28, 2006, is no longer a barrier blocking the final approval of your ANDA. Our office has received a letter from Martec Scientific, Inc. (Martec) dated September 20, 2007, in which Martec indicated their desire to relinquish their right to the 180-day exclusivity for this drug product. Therefore, the agency is no longer blocked from approving your ANDA.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution testing should be conducted in 50 mL of water at 37°C using USP Apparatus VII at 30 cycles per minute. The test product should meet the following "interim" specifications:

Time (hours)	Range
4 hr	NMT 14%
12 hr	39-75%
24 hr	NLT 75%

The "interim" dissolution tests and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the proposed final

specifications are tighter than the "interim" specifications. In all other instances, the data should be submitted in the form of a Prior Approval Supplement.

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 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,

(See appended electronic signature page)

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
10/3/2007 11:42:38 AM
for Gary Buehler