DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 77-127

Food and Drug Administration
Rockville MD 20857

NOV 21 2005

Osmotica Pharmaceutical Corp.
Attention: Mark S. Aikman
Building B, Suite 200
4800 N. Federal Highway
Boca Raton, FL 33431

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 19, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act (the Act), for Nifedipine Extended-release Tablets USP, 30 mg and 60 mg.

Reference is also made to your amendments dated April 19, May 5, and August 12, 2005.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Nifedipine Extended-release Tablets USP, 30 mg and 60 mg, to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Procardia® XL Tablets, 30 mg and 60 mg, respectively, of Pfizer Laboratories. Your dissolution testing should be incorporated into the stability and quality contol program using the same USP method proposed in your application.

The listed drug product (RLD) referenced in your application, Procardia(R) XL Tablets, 30 mg and 60 mg, of Pfizer Laboratories, is subject to a period of patent protection. As noted in the agency's publication entitled 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 application contains a paragraph IV certification to the '446 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that the '446 patent is invalid and will not be infringed by your manufacture, use, or sale of Nifedipine Extended-release Tablets USP, 30 mg and

60 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 '446 patent which was the subject of the paragraph IV certification. This action must have been brought against Osmotica prior to the expiration of forty-five days from the date the notice you provided under Paragraph (2)(B)(i) was received by the NDA/patent holder(s). 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 of the '446 patent was brought against Osmotica within the statutory forty-five day period.

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

Postmarketing reporting requirements for this abbreviated application 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