DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-503

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 20, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxybutynin Chloride Extended-release Tablets, 5 mg, 10 mg, and 15 mg.

Reference is also made to your amendments dated April 24, July 5, August 29, October 19, and December 11, 2007; July 24, November 24, and December 15, 2008; and January 7, and January 13, 2009.

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 Oxybutynin Chloride Extended-release Tablets, 5 mg, 10 mg, and 15 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Ditropan XL Extended-release Tablets, 5 mg, 10 mg, and 15 mg, respectively, of Ortho McNeil Janssen Pharmaceutica Products LP. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The "interim" dissolution specifications are as follows:

> Dissolution testing should be conducted according to USP 30, in 50 mL of simulated gastric fluid without enzymes at 37°C, using USP apparatus 7, 30 cycles per minute; 2- to 3-

cm amplitude. The test product should meet the following "interim" specifications:

Time (hours)	Percent Dissolved
4	NMT 25
10	40-65
24	NLT 75

The "interim" dissolution test(s) 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 final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Ortho McNeil's Ditropan XL Extended-release Tablets, is subject to periods of patent protection. The following patents and their expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,674,895 (the '895 patent)	November 22, 2015
5,840,754 (the '754 patent)	November 22, 2015
5,912,268 (the '268 patent)	November 22, 2015
6,262,115 (the '115 patent)	November 22, 2015
6,919,092 (the '092 patent)	November 22, 2015

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Oxybutynin Chloride Extended-release Tablets, 5 mg, 10 mg, and 15 mg, under this ANDA. You notified the agency that Osmotica Pharmaceutical Corp. (Osmotica) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of any of these patents 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)(2)(B)(iii).

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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National

Library of Medicine for public dissemination. For administrative purposes, please designate this submission as *"Miscellaneous Correspondence - SPL for Approved ANDA 78-503".*

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
2/4/2009 02:45:38 PM
Deputy Director, for Gary Buehler