DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-644

NOV 9 2006

Mylan Pharmaceuticals Inc.
Attention: S. Wayne Talton
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 21, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Oxybutynin Chloride Extended-release Tablets, 10 mg.

Reference is made to the Tentative Approval letter issued by this office on January 12, 2005, and to your amendments dated February 18, June 9, and July 27 (two amendments), 2004; and August 19, September 16, September 21, and October 27, 2005. We also acknowledge receipt of your correspondence dated July 19, August 31, September 16, and September 29, 2005, and August 17, 2006, regarding the '092 patent as noted below and informing the agency of the outcome of your patent litigation regarding the '355 patent.

We have completed the review of this ANDA as amended, 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 Oxybutynin Chloride Extended-release Tablets, 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Ditropan XL Extended-release Tablets, 10 mg, of Alza Corporation. 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:

Time	Percent Dissolved
2 hr:	(b)(4)
4 hr:	
8 hr:	
16 hr:	

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 when 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 listed drug product referenced in your ANDA, Ditropan XL Extended-release Tablets, 10 mg, of Alza Corporation, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication entitled 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
6,124,355 (the '355 patent)	November 22, 2015
6,262,115 (the '115 patent)	November 22, 2015
6,919,092 (the '092 patent)	November 22, 2015

*with pediatric exclusivity

Your ANDA contains paragraph IV patent certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, sale, offer for sale, or importation of Oxybutynin Chloride Extended-release Tablets, 10 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 Mylan Pharmaceuticals, Inc. (Mylan) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. This action must have been brought against

Mylan prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B) was received by the NDA/patent holder(s). You have notified the agency that Mylan complied with the requirements of section 505(j)(2)(B) of the Act. As a result, litigation for infringement of the '355 patent was brought against Mylan in the United States District Court for the Northern District of West Virginia (Alza Corporation v. Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc., Civil Action No. 1:03-cv-158). Following receipt of the tentative approval letter, you informed the agency that Mylan prevailed in the district court with respect to the finding that Mylan did not infringe the asserted claims of the '355 patent. Therefore, under section 505(j)(5)(B)(iii)(I), this court decision renders the ANDA eligible for approval. Furthermore, you informed the agency that on October 11, 2005, Alza appealed the district court decision, and that on September 6, 2006, the U.S. Court of Appeals for the Federal Circuit affirmed the district court's holding that Mylan's product does not infringe the asserted claims of the patent and that the asserted claims are invalid.

The agency recognizes that Mylan was not sued within the 45-day period on any of the other listed patents.

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Oxybutynin Chloride Extended-release Tablets, 10 mg, to each of the listed patents. Therefore, with this approval, Mylan is eligible for 180-days of market exclusivity for Oxybutynin Chloride Extended-release Tablets, 10 mg. This exclusivity, which is provided for under section 505(j)(5)(8)(iv) of the Act,[1] will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit correspondence to the ANDA informing the agency of the date the exclusivity begins to run.

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.

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[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

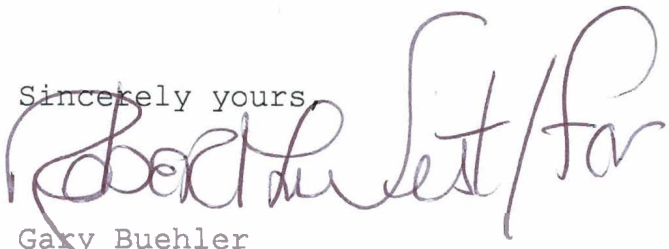
Post-marketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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 materials for any subsequent advertising or promotional campaign be submitted to our 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