DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-873

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 September 9, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Paroxetine Hydrochloride Extended-release Tablets, 12.5 mg (base) and 25 mg (base).

Reference is also made to the tentative approval letter issued by this office on May 30, 2007, and to your amendments dated February 15, 2006; and June 11, June 20, and June 27, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been provided 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 Paroxetine Hydrochloride Extended-release Tablets, 12.5 mg (base) and 25 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Paxil CR Extended-release Tablets, 12.5 mg (base) and 25 mg (base), respectively, of GlaxoSmithKline (GSK). 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:

> For the acid stage, dissolution testing should be conducted for 2 hours in 750 mL of 0.1N HCl. For the buffer stage, dissolution testing should be conducted for 12 hours in 0.05M tris buffer (pH 7.5). Temperature for both stages

should be 37°C using USP apparatus I (basket) at 100 rpm. Both strengths of the test product should meet the following "interim" specifications:

	Time (hours)	Percent Dissolved
Acid Stage	2	---
Buffer Stage	2	---
	4	---
	12	---

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

The RLD upon which you have based your ANDA, GSK's Paxil CR Extended-release Tablets, 12.5 mg (base) and 25 mg (base), is subject to periods of patent protection. The following patents and 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
4,721,723 (the '723 patent)	June 29, 2007
5,422,123 (the '123 patent)	December 6, 2012
5,789,449 (the '449 patent)	July 6, 2009
5,872,132 (the '132 patent)	November 19, 2015
5,900,423 (the '423 patent)	November 19, 2015
6,121,291 (the '291 patent)	September 17, 2017
6,133,289 (the '289 patent)	November 19, 2015
6,548,084 (the '084 patent)	January 19, 2017
7,229,640 (the '640 patent)	July 19, 2016

With respect to the '123, '132, '423, '291, '289, and '084 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 Paroxetine Hydrochloride Extended-release Tablets 12.5 mg (base) and 25 mg (base), 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 these patents that were the subjects of the paragraph IV certifications. You have notified the agency that Mylan complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Mylan 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).

With respect to the ‘640 patent, your ANDA contains a paragraph IV certification stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Paroxetine Hydrochloride Extended-release Tablets 12.5 mg (base) and 25 mg (base), under this ANDA. You have notified the agency that Mylan complied with the requirements of section 505(j)(2)(B) of the Act. The agency recognizes that, under the Act (as amended in 2003 by the Medicare Prescription Drug, Improvement and Modernization Act) no 30-month of approval stay can arise from this certification and, therefore, the ‘640 patent does not present a barrier to approval of this ANDA at this time.

With respect to the '449 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act indicating that this is a method of use patent, and that it does not claim any indication for which you are seeking approval under your ANDA.

With respect to the ‘723 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that Mylan will not market Paroxetine Hydrochloride Extended-release tablets, 12.5 mg (base) and 25 mg (base), prior to the expiration of this patent. The agency recognizes that the pediatric exclusivity period attaching to the ‘723 patent expired on June 29, 2007.

With respect to 180-day generic drug exclusivity, the agency has concluded that Mylan was the first applicant to submit a substantially complete ANDA with a paragraph IV certification for Paroxetine Hydrochloride Extended-release Tablets 12.5 mg

(base) and 25 mg (base). Therefore, with this approval, Mylan is eligible for 180 days of generic drug exclusivity for Paroxetine Hydrochloride Extended-release Tablets 12.5 mg (base) and 25 mg (base). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this 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.

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
6/29/2007 09:55:16 AM
for Gary Buehler