DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078783

Par Pharmaceutical, Inc.
Attention: Julie Szozda, Submissions Manager
Regulatory Affairs
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 6, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Tramadol Hydrochloride Extended Release Tablets, 100 mg and 200 mg.

Reference is also made to the tentative approval letter issued by this office on July 8, 2009, and to your amendments dated March 22, July 20, and September 5, 2007; February 7, May 15, July 24, and September 12, 2008; and January 20, and October 2, 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 Tramadol Hydrochloride Extended Release Tablets, 100 mg and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Ultram ER Extended-release Tablets, 100 mg and 200 mg, respectively, of Biovail Laboratories International, SRL (Biovail).

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:

Medium: 0.1N HCl
Apparatus: USP Type I (Basket)
Temperature: 37°C +/-0.5°C
Speed: 75 rpm
Volume: 900 mL

Time (hours)	Percent Dissolved
2	(b) (4)
4	
8	
10	
16	

These "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 these "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 reference listed drug (RLD) upon which you have based your ANDA, Ultram ER Tablets, 100 mg and 200 mg of Biovail Labs International (Biovail), is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations(the "Orange Book"), U.S. Patent Nos. 6,254,887 (the '887 patent) and 7,074,430 (the '430 patent) are both scheduled to expire on May 10, 2014.

With respect to the '430 patent, the agency recognizes that this patent was late listed with respect to your ANDA and no certification is required. See 21 CFR 314.94(a)(12)(vi).

With respect to the '887 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tramadol Hydrochloride Extended Release Tablets, 100 mg and 200 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 Par Pharmaceutical, Inc. (Par) for infringement of the '887 patent that was the subject of the

paragraph IV certification. This action must have been brought against Par prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Par complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Par for infringement of the '887 patent in the United States District Court for the District of Delaware [Purdue Pharma Products L.P., Napp Pharmaceutical Group Ltd., Biovail Laboratories International, SRL, and Ortho-McNeil, Inc., v. Par Pharmaceutical, Inc.,and Par Pharmaceutical Companies, Inc., Civil Action No. 07-255-KAJ]. You have also notified the agency that the court entered a Judgment Order on August 14, 2009, in favor of Par with the finding that that the '887 patent is invalid. Therefore, under section 505(j)(5)(B)(iii), your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Par was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '887, and '430 patents. Therefore, with this approval, Par is eligible for 180 days of generic drug exclusivity for Tramadol Hydrochloride Extended Release Tablets, 100 mg and 200 mg. 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.

We 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 505-1(i).

Postmarketing reporting requirements for this ANDA 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 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(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, 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 078783".***

Sincerely yours,

{See appended electronic signature page}

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-78783	ORIG-1	PAR PHARMACEUTICAL DBA KALI LABORATORIES INC SUB PAR PHARMACEUTICAL COMPANIES INC	TRAMADOL HYDROCHLORIDE

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
11/13/2009
Deputy Director, for Gary Buehler