DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078540

Par Pharmaceutical, Inc.
Attention: Julia 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 October 10, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Propafenone Hydrochloride Extended-release Capsules, 225 mg, 325 mg, and 425 mg.

Reference is also made to your amendments dated January 10, February 7, June 1, and November 28, 2007; July 30, 2008; May 19, June 25, and July 16, 2009; and March 16, June 4, June 7, June 22, July 26, August 17, August 25, and September 8, 2010.

In addition, we acknowledge receipt of your correspondences dated November 9, 2006; February 22, July 19, 2007; and April 23, 2009, addressing the patent issues associated with this ANDA.

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 Propafenone Hydrochloride Extended-release Capsules, 225 mg, 325 mg, and 425 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Rythmol SR Capsules 225 mg, 325 mg and 425 mg, respectively, of GlaxoSmithKline, LLC.

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:

> The dissolution testing should be conducted in 900 mL of 0.08 M HCl for the first two (2) hours, followed by 1000 mL of pH 6.8 Phosphate Buffer for 2-12 hours, at 37°C ± 0.5°C using USP Apparatus II (paddle) @ 50 rpm (The second medium is obtained by adding a buffer concentrate to the initial HCl medium). The test product should meet the following "interim" specifications:

Time (Hours)	Percent Dissolved
1	(b) (4)
4	
12	

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 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, GSK's (formerly Reliant Pharmaceuticals Inc.) Rythmol SR Capsules, 225 mg, 325 mg, and 425 mg, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,681,588 (the '588 patent), is scheduled to expire on October 28, 2014.

Your ANDA contains a paragraph IV certification to the '588 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Propafenone Hydrochloride Extended-release Capsules, 225 mg, 325 mg, and 425 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 listed '588 patent. You have notified the agency that Par complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '588 patent was brought against Par within the statutory 45-day period in the United

States District Court for the District of Delaware [Reliant Pharmaceuticals, Inc., v. Par Pharmaceutical, Inc., Civil Action No. 06-774]. You have also notified the agency that the litigation was dismissed; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity for Propafenone Hydrochloride Extended-release Capsules, 225 mg, 325 mg, and 425 mg, we note that Par was the first ANDA applicant to submit a substantially complete ANDA for Propafenone Hydrochloride Extended-release Capsules, 225 mg, 325 mg, and 425 mg with a paragraph IV certification to the '588 patent. Therefore, with this approval, Par may be eligible for 180-days of generic drug exclusivity for Propafenone Hydrochloride Extended-release Capsules, 225 mg, 325 mg, and 425 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, begins to run from the date of commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins. The agency notes that Par failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the Act. However, the agency is not making a formal determination at this time of Par's eligibility for 180-day generic drug exclusivity. It will do so only if another applicant becomes eligible for approval within 180 days after Par begins commercial marketing of Propafenone Hydrochloride Extended-release Capsules, 225 mg, 325 mg, and 425 mg.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] 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 (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

10/18/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.