ANDA 78-110

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: Par Pharmaceutical, Inc. TEL: 845-639-5128

ATTN: Julie Szoda FAX: 845-639-5201

FROM: Theresa Liu PROJECT MANAGER: (240) 276-8555

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated December 29, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Ropinirole Hydrochloride Tablets, 0.25 mg (base), 0.5 mg (base), 1 mg (base), 2 mg (base), 3 mg (base), 4 mg (base), and 5 mg (base).

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-110

Par Pharmaceutical, Inc.
Attention: Julie Szozda
One Ram Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 29, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ropinirole Hydrochloride Tablets, 0.25 mg (base), 0.5 mg (base), 1 mg (base), 2 mg (base), 3 mg (base), 4 mg (base), and 5 mg (base).

Reference is made to the first tentative approval letter issued by this office on May 15, 2007 and the second tentative approval letter on August 8, 2007. Reference is also made to your amendments dated July 19, September 19, and December 14, 2006; March 4 and 12, 2008.

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 Ropinirole Hydrochloride Tablets, 0.25 mg (base), 0.5 mg (base), 1 mg (base), 2 mg (base), 3 mg (base), 4 mg (base), and 5 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Requip Tablets, 0.25 mg (base), 0.5 mg (base), 1 mg (base), 2 mg (base), 3 mg (base), 4 mg (base), and 5 mg (base), respectively, of GlaxoSmithKline. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The reference listed drug (RLD) upon which you have based your ANDA, Requip Tablets, 0.25 mg (base0, 0.5 mg (base), 1 mg (base), 2 mg (base), 3 mg (base), 4 mg (base), and 5 mg (base), of GlaxoSmithKline, 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. 4,824,860 (the '860 patent), is scheduled to expire on May 19, 2008.

Your application contains a patent statement under section 505(j)(2)(A)(viii) of the Act indicating that the '860 patent is method-of-use patent, and that the claim (U-212) of this patent is not included as an indication for which you are seeking approval under this ANDA.

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/

Gary Buehler
5/5/2008 09:52:38 AM