DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-463

Par Pharmaceutical, Inc.
Attention: Michelle Bonomi-Huvala
Vice President, Regulatory Affairs
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 22, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Nateglinide Tablets, 60 mg and 120 mg.

Reference is also made to the tentative approval letter issued by this office on August 10, 2006, and to your amendments dated May 11, and July 7, 2005; and March 13, March 27, April 7, and July 1, 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 Nateglinide Tablets, 60 mg and 120 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Starlix Tablets, 60 mg and 120 mg, respectively, of Novartis Pharmaceuticals Corporation (Novartis). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Novartis' Starlix Tablets, is subject to periods of patent protection. The following patents and their expiration dates 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
5,463,116 (the ‘116 patent)	October 21, 2012
5,488,150 (the ‘150 patent)	January 30, 2013
6,559,188 (the ‘188 patent)	September 17, 2019
6,641,841 (the ‘841 patent)	November 14, 2017
6,844,008 (the ‘008 patent)	November 14, 2017
6,878,749 (the ‘749 patent)	September 15, 2020
RE34878 (the ‘878 patent)	September 8, 2009

With respect to the ‘749 patent, FDA has determined that information on this patent was submitted to FDA by the NDA holder (a) after the date of the submission of your ANDA, and (b) more than 30 days after the patent was issued by the U.S. Patent and Trademark Office. Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of the submission of the patents was required to submit an amended patent certification to address the ‘749 patent. You elected not to submit an amended patent certification with respect to this patent.

With respect to the ‘116, ‘150, ‘188, ‘841, and ‘008 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Nateglinide Tablets, 60 mg and 120 mg, under this ANDA. You have notified the agency that Par Pharmaceutical, Inc. (Par) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the ‘116, ‘150, ‘188, ‘841, or ‘008 patents was brought against Par within the statutory 45-day period described in section 505(j)(5)(B)(iii).

With respect to the ‘878 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of the ‘878 patent on September 8, 2009. Because of the expiration of this patent, your ANDA is now eligible for approval.

Par was one of the first applicants to submit a substantially complete ANDA with paragraph IV certifications to the ‘116, ‘150, ‘188, ‘841, and ‘008 patents. Therefore, Par is eligible for 180 days of generic drug exclusivity for Nateglinide Tablets, 60 mg and 120 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 commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit

correspondence to this ANDA informing the agency of the date you begin commercial marketing.

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 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.

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/oc/datacouncil/spl.html, 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 77-463***".

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-77463	ORIG-1	PAR PHARMACEUTICAL INC	NATEGLINIDE

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
09/09/2009
Deputy Director, for Gary Buehler