DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 77-463

AUG 10 2006

Par Pharmaceutical, Inc.
Attention: Julie Szozda
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 your amendments dated September 19, 2005; January 18, April 7, and May 4, 2006.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved.** This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The referenced listed drug product (RLD) upon which you have based your ANDA, Starlix Tablets, 60 mg and 120 mg, of Novartis Pharmaceuticals Corporation, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

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

The '749 patent was not listed with the agency by the NDA holder when the Office of Generic Drugs (OGD) received your ANDA on December 22, 2004. Because the agency regards the '749 patent as "late-listed" with respect to your ANDA, you are not required to amend your pending ANDA to contain a certification to this patent. See 21 CFR 314.94(a)(12)(vi).

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '116, '150, '188, '841, and '008 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 '116, '150, '188, '841, or '008 patents was brought against Par 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).

Finally, 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. Therefore, final approval cannot be granted until the '878 patent expires on September 8, 2009. It is for this reason that the agency is tentatively approving your ANDA at this time.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval, and it should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated

clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the Orange Book. Should you believe that there are grounds for issuing the final approval letter prior to September 8, 2009, you should amend your ANDA accordingly.

For further information on the status of this application, or prior to submitting additional amendments, please contact Jeanne Skanchy, Project Manager, at 301-827-9275.

Sincerely yours,

Robert Lee Sist/for

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