



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078966

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 April 30, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg and 40 mg/1100 mg.

Reference is made to the tentative approval letter issued by this office on October 30, 2009, and to your amendments dated February 5, 2008; May 6, 2009; and March 15, April 21, and April 22, 2010.

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 Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg and 40 mg/1100 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zegerid Capsules, 20 mg/1100 mg and 40 mg/1100 mg, respectively, of Santarus, Inc. (Santarus). 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, Santarus' Zegerid Capsules, 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") for this drug product:

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
6,489,346 (the '346 patent)	July 16, 2016
6,645,988 (the '988 patent)	July 16, 2016
6,699,885 (the '885 patent)	July 16, 2016
7,399,772 (the '772 patent)	July 16, 2016

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg and 40 mg/1100 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 litigation for infringement of the '346, '988, and '885 patents was brought against Par within the statutory 45-day period in the United States District Court for the District of Delaware [Santarus, Inc. and the Curators of the University of Missouri v. Par Pharmaceutical, Inc., Civil Action No. 07-551]. You have also notified the agency that the court decided that the '346, '988, and '885 patents are invalid, unenforceable, or not infringed; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval. We note that the '772 patent was not listed at the time your ANDA was submitted.

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 '346, '988, '885, and '772 patents. Therefore, with this approval, Par is eligible for 180 days of generic drug exclusivity for Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg and 40 mg/1100 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.

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.

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. For administrative purposes, please designate this submission as "**LABELING/SPL FINAL for Approved ANDA 078966**".

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- ANDA-78966	----- ORIG-1	----- PAR PHARMACEUTICA L	----- OMEPRAZOLE SODIUM BICARBONATE

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
05/25/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.