DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-487

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 28, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Famciclovir Tablets, 125 mg, 250 mg and 500 mg.

Reference is also made to the tentative approval letter issued by this office on June 26, 2007, and to your amendments dated May 4, 2005, and July 6, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been provided 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 Famciclovir Tablets, 125 mg, 250 mg, and 500 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Famvir Tablets 125 mg, 250 mg, and 500 mg, respectively, of Novartis Pharmaceuticals Corporation. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, Famvir Tablets, 125 mg, 250 mg, and 500 mg, of Novartis Pharmaceuticals Corporation (Novartis), 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
5,246,937 (the '937 patent)	September 21, 2010
5,840,763 (the '763 patent)	September 1, 2015
5,866,581 (the '581 patent)	October 4, 2014
5,916,893 (the '893 patent)	September 1, 2015
6,124,304 (the '304 patent)	October 4, 2014

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Famciclovir Tablets, 125 mg, 250 mg and 500 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 TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. This action must have been brought against TEVA prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against TEVA for infringement of the '937 patent in the United States District Court for the District of New Jersey [Novartis Pharmaceuticals Corporation, Novartis Pharma AG and Novartis International Pharmaceutical Ltd. v. TEVA Pharmaceuticals USA, Inc., Civil Action No. 05-1887]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, the agency has concluded that TEVA was the first ANDA applicant to submit a substantially complete ANDA containing a paragraph IV certification to the listed patents noted above. Therefore, with this approval, TEVA is eligible for 180-days of generic drug exclusivity for Famciclovir Tablets, 125 mg, 250 mg and 500 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 first 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.

Postmarketing reporting requirements for this ANDA application 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