DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-487

TEVA Pharmaceuticals USA
Attention: Philip Erickson
1090 Horsham Road
PO 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 your amendments dated October 12, 2005; and January 5, May 12 and 17, October 6, and November 11, 2006; and February 21, April 30, May 11, and June 22, 2007.

We have completed the review of this ANDA and have concluded that based upon the information you have presented to date, 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 of the facilities used in the manufacture 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 reference listed drug (RLD) upon which you have based your ANDA, Famvir of Novartis Pharmaceutical Corporation (Novartis) 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
5,246,937 (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 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 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 action is brought against TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of the patents that were the subjects of paragraph IV certifications. This action must be brought against TEVA prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B) was received by the NDA/patent holder(s). You notified the Agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and within the statutory 45-day period litigation for infringement of the '937 patent was brought against TEVA 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]. This litigation is pending.

Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii)[1] or such shorter or longer period as the court may have ordered, or,

[1] Because information on the '937 patent was submitted before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) was enacted. See MMA § 1101(c)(3).

b. the date the court decides[2] that the '937 patent is invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act), or

c. the '937 patent has expired, and

2. The agency is assured there is no new information that would affect whether final approval should be granted.

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 include a copy of a court decision, or a settlement or licensing agreement, as appropriate. 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

[2] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 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.”

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Ted Palat, Project Manager, at 301-827-5849.

Sincerely yours,

{see appended electronic signature page}

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