



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 078278

Watson Laboratories, Inc.  
Attention: Janie M. Gwinn  
Director, Regulatory Affairs  
311 Bonnie Circle  
Corona, CA 92880

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 24, 2006, 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 June 4, 2007; March 20, 2008; September 25, October 7, October 12, November 20, and December 14, 2009; and June 11, July 23, and August 26, 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 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, of Novartis Pharmaceuticals Corporation. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The reference listed drug (RLD) referenced in your application, Famvir Tablets, 125 mg, 250 mg, and 500 mg of Novartis Pharmaceuticals Corporation, is subject to periods of patent protection. The following patents and their expiration dates (with pediatric exclusivity extension) 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>
5,246,937 (the '937 patent)	March 21, 2011
5,840,763 (the '763 patent)	March 1, 2016
5,866,581 (the '581 patent)	April 4, 2015
5,916,893 (the '893 patent)	March 1, 2016
6,124,304 (the '304 patent)	April 4, 2015

Your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that the '937, '763, '581, '893, and '304 patents are method of use patents, and that these patents do not claim any proposed indication for which you are seeking approval under your ANDA.

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 505-1(i).

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] 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 (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

<http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible via publicly available labeling repositories.

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-78278	----- ORIG-1	----- WATSON LABORATORIES INC	----- FAMCICLOVIR

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ROBERT L WEST  
09/14/2010  
Deputy Director, Office of Generic Drugs  
for Keith Webber, Ph.D.