



NDA 20363/S-38
NDA 20363/S-40

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Raffy Chilingirian
Manager, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Chilingirian:

Please refer to your Supplemental New Drug Applications (sNDA), 20363/S-38, received April 15, 2011, and 20363/S-40, received August 25, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Famvir (famciclovir) Tablets 125 mg, 250 mg, and 500 mg.

For sNDA 20363/S-38, we acknowledge receipt of your amendments dated November 09, 2011, January 17, 2012, and February 03, 2012.

This "Prior Approval" sNDA provides for revisions to the "Pediatric Use" section of the package insert to add information from a pediatric study in patients aged 12 years to < 18 years of age with recurrent herpes labialis.

For NDA 20363/S-40, we acknowledge receipt of your amendments dated September 27, 2011, December 7, 2011 and January 27, 2012.

This "Prior Approval" sNDA provides for revisions to the ADVERSE REACTIONS, Postmarketing Experience section to include angioedema in the skin and subcutaneous tissue disorders section, the USE IN SPECIFIC POPULATIONS, Patients with Hepatic Impairment section and the CLINICAL PHARMACOLOGY, Pharmacokinetics section to include information regarding use in patients with severe hepatic impairment.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the package insert and patient package insert enclosed, with the

addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>;

instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call , Abiola Olagundoye-Alawode, Pharm.D., regulatory project manager at (301) 796-3982 or (301) 796- 1500.

Sincerely yours,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DEBRA B BIRNKRANT
02/09/2012