

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

203791Orig1s000

Trade Name: SITAVIG Buccal Tablet, 50 mg

Generic Name: acyclovir

Sponsor: BioAlliance Pharma

Approval Date: April 12, 2013

Indications: Treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

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APPROVAL LETTER



NDA 203791

NDA APPROVAL

BioAlliance Pharma
c/o Regulatory Compliance Initiatives, Inc.
Attention: James Carter, PhD
US Agent
PO Box 95651
Las Vegas, NV 89193

Dear Dr. Carter:

Please refer to your New Drug Application (NDA), received March 12, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SITAVIG (acyclovir) Buccal Tablet, 50 mg.

We acknowledge receipt of your amendments dated May 7, 2012, June 6, 2012, June 15, 2012, June 26, 2012, June 26, 2012, July 9, 2012, July 12, 2012, July 16, 2012, July 20, 2012, August 1, 2012, August 7, 2012, August 29, 2012, October 19, 2012, November 13, 2012, November 19, 2012, December 5, 2012, January 4, 2013, February 12, 2013, March 7, 2013, March 25, 2013, and April 09, 2013.

This new drug application provides for the use of SITAVIG (acyclovir) Buccal Tablet, 50 mg for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

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 enclosed labeling (text for the package insert, text for the patient package insert, and text for the instructions for use). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE-CONTAINER LABELS

Submit final printed carton and immediate-container labels that are identical to the carton and immediate-container labels submitted on April 09, 2013, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 203791.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages birth to less than or equal to 6 years because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric subpopulation. SITAVIG (acyclovir) Buccal Tablet is a mucoadhesive buccal tablet and is to be applied or placed on the gum until the drug completely dissolves. This type of application may be unsafe in young children due to potential choking hazards.

We are deferring submission of your pediatric study for ages greater than 6 years to less than 18 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. This required study is listed below.

2037-1 Deferred pediatric study under PREA to evaluate the safety of SITAVIG (acyclovir) in pediatric patients greater than 6 years to less than 18 years of age with recurrent herpes labialis and to assess duration of herpes simplex virus (HSV) episodes in the treated population. At least 100 treated subjects, distributed across the age range, must be evaluated.

Final Protocol Submission: 01/31/2014
Study Completion: 06/31/2017

Final Report Submission: 12/31/2018

Submit the protocol to your IND 77,812, with a cross-reference letter to this NDA.

Reports of this required pediatric postmarketing study must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

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

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see 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 Sohail Mosaddegh, PharmD, Regulatory Project Manager, at (301) 796-4876 or (301) 796-1500.

Sincerely yours,

{See appended electronic signature page}

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

Enclosures:

Content of Labeling (USPI, PPI, IFU)
Container/carton labeling

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

/s/

JEFFREY S MURRAY
04/12/2013