DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-404 **NDA APPROVAL**

BioAlliance Pharma
c/o Beckloff Associates, Inc.
Attention: Lavonne M. Patton, Ph.D.
Director
7400 West 110th Street, Suite 300
Overland Park, Kansas 66210

Dear Dr. Patton:

Please refer to your June 15, 2009 New Drug Application (NDA), received June 16, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ORAVIG (miconazole), buccal tablets, 50 mg.

We acknowledge receipt of your submissions dated:

August 11, 2009	September 29, 2009	October 15, 2009
October 16, 2009	October 28, 2009	December 29, 2009
January 14, 2010	January 22, 2010	February 25, 2010
April 13, 2010		

This new drug application provides for the use of ORAVIG (miconazole), buccal tablets, 50 mg, for the treatment of oropharyngeal candidiasis.

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 content of labeling submitted on April 13, 2010, a copy of which is attached to this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

We also acknowledge your April 13, 2010, submission containing final printed carton and container labels, copies of which are attached to this letter.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit 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 to the enclosed content of labeling (text for the package insert and patient labeling), which was submitted on April 13, 2010. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-404**."

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 are waiving the pediatric study requirement for ages 0 to 5 years due to the risk of chocking on the product and the inability to comply with use instructions in this age group.

We are deferring submission of your pediatric study for ages > 5 to ≤17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act 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 Federal Food, Drug, and Cosmetic Act. This required study is listed below.

1. Deferred pediatric study under PREA investigating ORAVIG safety, pharmacokinetics, efficacy and compliance with use instructions in patients with oropharyngeal candidiasis ages > 5 to ≤17 years.

   Date of Protocol Submission: December 31, 2010
   Date of Study Completion: June 30, 2013
   Final Report Submission: March 31, 2014

Submit final study reports to this NDA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated "**Required Pediatric Assessment(s)**".

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
Division of Drug Marketing, Advertising, and Communications
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 inserts, 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 Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.
Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Judit Milstein, Chief Project Management Staff, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, MD
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Content of Labeling
Carton and Container Labels

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22404	ORIG-1	BIOALLIANCE PHARMA	ORAVIG (miconazole) buccal tablets

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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.

/s/

RENATA ALBRECHT
04/16/2010