DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22404/S-002

SUPPLEMENT APPROVAL

BioAlliance Pharma
c/o Beckloff Associates, Inc.
Attention: Lavonne M. Patton, PhD
Authorized U.S. Agent
Commerce Plaza II, Ste 300
7400 West 110th Street
Overland Park, KS 66210

Dear Dr. Patton:
Please refer to your Supplemental New Drug Application (sNDA) dated January 11, 2011, received January 12, 2011,submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ORAVIG (miconazole) Buccal Tablets, 50 mg.

We acknowledge receipt of your amendment dated February 18, 2011.

This "Prior Approval" supplemental new drug application provides for the following revision to the package insert:

In the FULL PRESCRIBING INFORMATION, 14 CLINICAL STUDIES/S*tudy in HIV Infected Patients*, footnote under Table 5 is revised as follows:

Table 5: Clinical Cure and Mycological Cure at the TOC Visit and Relapse at Days 35-38 in HIV Infected Patients

	ORAVIG 50 mg N=290[a] (%)	Clotrimazole troches N=287[a] (%)
Clinical cure†	176 (60.7%)	187 (65.2%)
Clinical relapse‡		
Yes[b]	48 (27.3%)	52 (27.8%)
No	124 (70.5%)	133 (71.1%)
Missing	4 (2.3%)	2 (1.1%)
Mycological cure	79 (27.2%)	71 (24.7%)

[a] Analysis population includes all randomized patients who took at least 1 dose of study medication. One randomized subject excluded from the ORAVIG arm.
[b] In those subjects who relapsed, the mean time to relapse was 15.3 days (SD 4.6) and 15.7 days (SD 6.6), in the ORAVIG and Clotrimazole treatment arms, respectively.
† Difference in clinical cure rates (ORAVIG ~~miconazole~~ Clotrimazole troche) was -4.5%, with a 95% CI: (-12.4%, 3.4%).
‡ Percentage based on those who had clinical cure.

We also note that the FULL PRESCRIBING INFORMATION: CONTENTS section of the package insert has been revised to add new 8.6 Hepatic Impairment and 8.7 Renal Impairment subsections. We will consider this revision as an editorial change that does not require our approval as the FULL PRESCRIBING INFORMATION section of the package insert already listed both 8.6 Hepatic Impairment and 8.7 Renal Impairment subsections.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, which is identical to the package insert submitted February 18, 2011.

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 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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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, Regulatory Project Manager, 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: Package Insert

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
04/08/2011