DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-517/S-050

SUPPLEMENT APPROVAL

Bioniche Pharma USA LLC
Attention: Delia Knight, MSc
Regulatory Affairs Manager
272 East Deerpath, Suite 304
Lake Forest, IL 60045

Dear Ms. Knight:

Please refer to your Supplemental New Drug Application (sNDA) dated July 14, 2010, received, July 16, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mefoxin (Cefoxitin for Injection, USP), 1g/10mL, 2g/20mL, 10g/100mL.

This "Changes Being Effected" supplemental new drug application provides for the following:

- Update Sponsor name from Merck & Co, to Bioniche Pharma, LLC.
- Addition of a new manufacturing site: Antibioticos do Brasil Ltda (ABL) at Rod. Gal. Milton Tavares de Souza- SP- 332, Kni 135 Cosmopolis, SP -Brazil - ZpC 13150-000 to the labeling.
- Clarifies the administration section to ensure proper administration of the drug product.
- Minor editorial changes.

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended with the agreed-upon labeling text and with the minor editorial revisions listed below for the 1g, 2g, and 10g vial carton labels:

For the 1g vial label:

- The statement "Sealed under nitrogen" should be moved so that it appears immediately following the sentence "Avoid exposure to temperatures above 50° C", since the product was sealed under nitrogen prior to constitution.

For the 2g vial label:

- The statement "Sealed under nitrogen" should be moved so that it appears immediately following the sentence "Avoid exposure to temperatures above 50° C", since the product was sealed under nitrogen prior to constitution.

For the 10g vial label:

- The statement "Sealed under nitrogen" should be moved so that it appears immediately following the sentence "Avoid exposure to temperatures above 50° C", since the product was sealed under nitrogen prior to constitution.

- Add the heading "Prior to constitution:" before the sentence, "Store dry material…" in order to be consistent with the label formats of the 1g and 2g vials.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on July 14, 2010**,** except with the revisions listed above, 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 titled "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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 50-517/S-050**." Approval of this submission by FDA is not required before the labeling is used.

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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

KATHERINE A LAESSIG
02/04/2011