DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 19-677/S-006

Bioniche Pharma USA, LLC
272 East Deerpath Road, Suite 304
Lake Forest, IL 60045

Attention: Rhonda Noll, B.Sc., C.E.T.
Senior Director Regulatory Affairs

Dear Ms Noll:

Please refer to your supplemental new drug application dated September 29, 2008, received September 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Enlon Plus (edrophonium chloride and atropine sulfate, USP) Injection.

We also acknowledge receipt of your submissions dated November 25, 2008, January 8, 9, February 17, and March 18, 2009.

This supplemental new drug application provides for changes to the manufacturing site and process as well as the addition of the latex warning to the carton and container labels and to the **WARNINGS** section of the package insert.

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

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and the carton and container labels submitted March 18, 2009.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-677/S-006.**" Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Sharon Turner-Rinehardt, Regulatory Health Project Manager, at (301) 796-2254.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia, and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Rigoberto Roca
4/1/2009 05:18:15 PM
for Bob Rappaport, M.D.