DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020111/S-007 **SUPPLEMENT APPROVAL**

Dennis M. Gronek
Gronek & Associates
233 South Wacker Drive
Suite 9300
Chicago, IL 60606

Dear Mr. Gronek:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on December 19, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DYNA-HEX 0.75 (chlorhexidine gluconate 0.75% solution).

We acknowledge receipt of your amendment dated March 14, 2013.

This "Changes Being Effected" supplemental new drug application provides for labeling revisions to add the following statement in the Directions section of *Drug Facts*:

> Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

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 agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical the DYNA-HEX 0.75® 4-oz, 8-oz, 16-oz, 30-oz, 32-oz, and 1-gal immediate container (bottle) labels submitted on March 14, 2013, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted 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 "**Final Printed Labeling for approved NDA 020111/S-007."** Approval of this submission by FDA is not required before the labeling is used.

We remind you that it is the sponsor's responsibility to ensure that all distributor labels are consistent with currently approved labeling.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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, contact Celia Peacock, Regulatory Project Manager, at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

COPY:
Bajaj Medical LLC
415 W. Pershing Road
Chicago, IL 60609-2788

ENCLOSURES:
Immediate container (bottle) label

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

/s/

JOEL SCHIFFENBAUER
05/08/2013