DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020111/S-009

SUPPLEMENT APPROVAL

Bajaj Medical, LLC.
Attention: Ram Chakroborty, Ph.D.
President
415 W. Pershing Rd.
Chicago, IL 60609

Dear Dr. Chakroborty:

Please refer to your supplemental new drug application (sNDA) dated and received May 25, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DYNA-HEX 0.75™ (chlorhexidine gluconate) solution, 0.75%.

This "Prior Approval" supplemental new drug application provides for the following changes:

- Adds an "Allergy alert" warning to labeling in accordance with the Agency's "Changes Being Effected" (CBE-0) Request Letter dated February 2, 2017

- Modifies labeling to incorporate various other revisions

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 and with the minor editorial revision listed below:

> Under the Drug Facts labeling "**Warnings**" heading, reformat the allergic reaction warning subheading by including a colon after the "t" to appear as "**Allergy alert:**" as required under 21 CFR 201.66(c)(5)(ii)(B).

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 must be identical to the labeling listed in the following table, must incorporate the change specified above, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date of Submission
4 fl oz immediate container (white HDPE round bottle)	August 25, 2017
8 fl oz immediate container (white HDPE round bottle)	August 25, 2017
16 fl oz immediate container (white HDPE round bottle)	August 25, 2017
32 fl oz immediate container (white HDPE round bottle)	August 25, 2017
128 fl oz immediate container (white HDPE round bottle)	August 25, 2017

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020111/S-009**." Approval of this submission by FDA is not required before the labeling is used.

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, call Laurie Buonaccorsi, Regulatory Project Manager, at (240) 402-6297.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Container Labeling

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

/s/

THERESA M MICHELE
11/20/2017