DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-779/S-023

SUPPLEMENT APPROVAL

B. Braun Medical, Inc.
Attention: Rebecca Stolarick
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Stolarick:

Please refer to your Supplemental New Drug Application (sNDA) dated March 18, 2014, received March 18, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cefazolin for Injection USP and Dextrose Injection, 1g and 2g.

This "Prior Approval" supplemental new drug application provides submission of post marketing requirement (PMR) information pursuant to PMR 1869-1, as listed in the January 13, 2012, approval letter for supplement 018.

APPROVAL & LABELING

We have completed our review of this supplemental application and have determined that your study report is acceptable. This supplemental application is approved. There are no labeling changes warranted at this time.

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}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective 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/

SUMATHI NAMBIAR
09/18/2014