DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-826/S-020

B.Braun Medical, Inc.
901 Marcon Boulevard
Allentown, PA 18109

Attention: Susan Olinger
Corporate Vice President, Regulatory Affairs

Dear Ms. Olinger:

Please refer to your supplemental new drug applications dated January 08, 2008, received January 08, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Theophylline in 5% Dextrose in the Excel® plastic container.

This "Changes Being Effected" supplemental new drug application provides for the addition of the following statement to the ADVERSE REACTION and OVERDOSAGE sections of the package insert: "Hypercalcemia has been reported in a patient with hyperthyroid disease at therapeutic theophylline concentrations."

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on January 08, 2008.

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 Sadaf Nabavian, Regulatory Project Manager, at (301) 796-2777.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research
Enclosure: Approved Labeling

Enclosure: Approved Labeling

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

/s/

Badrul Chowdhury
4/8/2008 04:26:00 PM