DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-649/S-043

Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, IL 60085-6730

Attention: Vicki Drews
Director, Global Regulatory Affairs

Dear Ms. Drews:

Please refer to your supplemental new drug application dated April 11, 2008, received April 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Theophylline in 5% Dextrose Injection, Viaflex plus container.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Pregnancy subsection of the PRECAUTIONS section of the Package Insert.

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 April 11, 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
10/17/2008 09:26:00 AM