



NDA 18-649/S-040

Baxter Healthcare Corporation  
Route 120 and Wilson Road  
Round Lake, IL 60073-0490

Attention: Marcia Marconi  
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated June 27, 2003, received June 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Theophylline in 5% dextrose injection, UPS in plastic container.

This "Changes Being Effected" supplemental new drug application provides the addition of a statement against use of this drug product in patients with a know allergy to corn or corn products to the CONTRAINDICATION section of the package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 27, 2003 (copy enclosed).

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, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ladan Jafari , Regulatory Project Manager, at (301) 827-1084.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

-----  
**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  
12/31/03 12:14:12 PM  
I concur