



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 19-211/S-040

Hospira, Inc.  
275 North Field Drive  
Dept. 0389, Bldg. H-2  
Lake Forest, IL 60045

Attention: Amanda Santoro  
Associate Global Regulatory Affairs

Dear Ms. Santoro:

Please refer to your supplemental new drug application dated April 14, 2008, received April 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Theophylline in 5% Dextrose Injection, USP, Flexible Plastic 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 14, 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

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/s/

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Badrul Chowdhury  
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