DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-872/S-031

McNeil Consumer Healthcare
Attention: Eileen M. Geisinger
Associate Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Geisinger:

Please refer to your supplemental new drug application dated December 17, 2008, received December 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8-Hour (650 mg acetaminophen) extended-release tablets.

We acknowledge receipt of your submissions dated February 13, and May 18, 2009.

This supplemental new drug application provides for the addition of the warning statement "Do not use [bullet] if you are allergic to acetaminophen or any of the inactive ingredients in this product" to the Drug Facts label for the Tylenol 8-Hour and Tylenol Arthritis Pain Relief products.

We have 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) for the Tylenol 8-Hour 100-count caplet immediate container and carton labels and the Tylenol Arthritis Pain 150-count caplet immediate container and carton labels submitted on February 13, 2009.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer

6/17/2009 07:05:30 AM