DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19872/S-048

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.
McNeil Consumer Healthcare Division
Attention: Eileen Harman
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Mail Stop 111
Fort Washington, PA 19034

Dear Ms. Harman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received, July 19, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tylenol® 8 HR Arthritis Pain (acetaminophen) extended-release tablet, 650 mg and Tylenol ® 8 HR Muscle Aches & Pain (acetaminophen) extended-release tablet, 650 mg.

This "Prior Approval" supplemental new drug application provides for:

- introduction of a new 100-ct stock keeping unit (SKU) configuration for Tylenol 8HR Arthritis Pain that will replace the approved 100-ct stand-alone immediate container SKU
- introduction of an additional 100-ct vertical label
- introduction of a dual principal display panel (PDP) carton redesign for the 225-ct Tylenol 8HR Arthritis Pain; one panel with the PDP in a horizontal orientation and the other panel with PDP in a vertical orientation
- change of the inner foil seal imprint to "TYLENOL"
- update of the Tamper-Evident Statement (TES) in Drug Facts label (DFL)
- introduction of a "tear open" strip to all cartons

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the labeling below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	**Date Submitted**
TYLENOL® 8 HR Arthritis Pain	
24-ct carton (bottle)	November 14, 2018
24-ct immediate container (bottle)	November 14, 2018
100-ct carton (bottle)	November 14, 2018
100-ct carton (bottle) - *Alternative*	November 28, 2018
100-ct immediate container (bottle)	November 14, 2018
225-ct carton (bottle) – *Dual PDP*	November 28, 2018
225-ct carton (bottle) – *Alternative without Dual PDP*	November 28, 2018
225-immediate container (bottle)	November 14, 2018
TYLENOL® 8 HR Muscle Aches & Pain	
24-ct carton (bottle)	November 14, 2018
24-ct immediate container (bottle)	November 14, 2018
100-ct carton (bottle)	November 14, 2018
100-ct immediate container (bottle)	November 14, 2018
"TYLENOL" Inner Seal	October 15, 2018

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 19872/S-048**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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 Tinya Sensie, Regulatory Project Manager at (240) 402-4230.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KAREN M MAHONEY
01/16/2019 09:47:55 AM