DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19872/S-044

SUPPLEMENT APPROVAL

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

Dear Ms. Harman:

Please refer to your Supplemental New Drug Application (sNDA) dated February 29, 2016, received February 29, 2016, and your amendments, submitted under section 505(b of the Federal Food, Drug, and Cosmetic Act (FDCA) for TYLENOL® 8 HR Arthritis Pain/ TYLENOL® 8 HR (acetaminophen) extended-release tablet; 650 mg.

This "Prior Approval" supplemental new drug application provides for the inclusion of slack fill requirements to comply with the California Slack Fill Regulations (California Business & Professional Code, Section 12606).

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 (FPL) must be identical to the submitted labeling (immediate container and carton labels listed below submitted on April 27, 2016), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Tylenol 8 HR Arthritis Pain

- 24-count outer carton and immediate container labels
- 100-count immediate container (bottle with peel-back Drug Facts) label (no outer carton)
- 225-count outer carton and immediate container labels
- 290-count outer carton and immediate container labels

Tylenol 8 HR Muscle Aches & Pain

- 24-count outer carton and immediate container labels
- 100-count outer carton and immediate container labels
- 225-count outer carton and immediate container labels

We remind you that the expiration date and lot numbers should be included on all labels submitted as final printed labeling.

Also, the flag "See New Warning" should be removed from the labels 6 months after marketing.

We note that the principal display panel contains a caplet image without an imprint. We remind you that images should represent the actual tablet and should reflect the imprint of the tablet in addition to showing the true size and color. We refer you to the draft guidance for industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.*

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 19872/S-044**." 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 and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
08/26/2016