DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019872/S-039

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare
Attention: Eileen Harman
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Harman:

Please refer to your Supplemental New Drug Application (sNDA) dated June 20, 2013, received June 21, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tylenol 8 HR Arthritis Pain (acetaminophen 650 mg) Extended-Release Tablet.

We acknowledge receipt of your amendments dated November 22 and 26, and December 16, 2013.

This "Prior Approval" supplemental new drug application proposes a graphic redesign for Tylenol 8 HR Arthritis Pain (acetaminophen 650 mg) Extended-Release.

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 and with the minor editorial revisions to the 225- and 290-count outer carton labels listed below:

1. In Drug Fact under **Warnings**, a hairline should be added to separate the overdose warning section from the previous section. The hairline should be placed following the "Keep out of reach of children" statement and before the overdose warning.

2. The location of the lot number should be indicated on the carton labels.

LABELING

Submit final printed labeling, with the revisions listed above, 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 labels listed below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

- 2-count professional sample pouch submitted November 22, 2013

- 50-count immediate container (bottle) submitted June 20, 2013 and outer carton submitted November 22, 2013 (representative of the 24-and 150-count SKUs)
- 100-count immediate container (bottle) label (no outer carton) submitted November 22, 2013
- 225-count immediate container (bottle) and outer carton submitted December 16, 2013
- 290-count immediate container (bottle) and outer carton submitted December 16, 2013

We remind you to submit all labels, as representative labels are not acceptable as FPL.

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 019872/S-039**." Approval of this submission by FDA is not required before the labeling is used.

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 Jade Pham, Regulatory Project Manager at (301) 796-7031.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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/

THERESA M MICHELE
12/20/2013