DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019872/S-036

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare
Attention: Nader Fatouhi, Ph.D.
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Dr. Fatouhi:

Please refer to your Supplemental New Drug Application (sNDA) dated June 23, 2011, received June 23, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tylenol® 8 Hour (acetaminophen) extended-release tablets, 650 mg.

We acknowledge receipt of your amendments dated December 1 and 13, 2011.

This "Changes Being Effected" supplemental new drug application proposed revisions to the overdose warning statement contained in the "Drug Facts" label because of redundancy due to the implementation of the organ specific warnings final rule ((21 CFR 201.326).

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 following enclosed labeling submitted December 1 and 13, 2011, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. FPL must be submitted for all the representative count sizes. Representative labeling will not be acceptable in the FPL submission.

Tylenol Arthritis Pain "caplets" (capsule-shaped tablets)

- 50-count immediate container (bottle) and carton labels
  - Representative of (24-, 150-, 190-, 225, and 290-count) immediate container (bottle) and carton labels
- 100-count peel-back "Drug Facts" label for the 100-count immediate (bottle) container label
- 2-count immediate container (pouch)

Tylenol Arthritis Pain "gelcaps" (gelatin-coated tablets)

- 40-count immediate container (bottle) and carton labels
    - Representative of (20- and 80-count) immediate container (bottle) and carton labels

Tylenol 8-Hour "caplets" (capsule-shaped tablet)
50-count immediate container (bottle) and carton labels
    - Representative of (24-, 100-, and 150-count)
- 2-count immediate container (pouch) label
- 6-count (3 x 2-count pouch) carton label

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 019872S-036**." 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 LT James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D., M.S.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosures: Carton and Immediate 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/

ANDREA LEONARD SEGAL
12/23/2011