DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019872/S-037

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.
Attention: Victoria Wagner-Weber
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Wagner-Weber:

Please refer to your Supplemental New Drug Application (sNDA) dated October 5, 2012, received October 5, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TYLENLOL Arthritis Pain (acetaminophen) Extended-Release Tablets, 650 mg.

We acknowledge receipt of your amendment dated December 20, 2012.

This "Prior Approval" supplemental new drug application proposes to add "8 HR" after "TYLENOL" to emphasize the dosing interval of the extended-release product.

We have completed our review of this application, as amended. Per 21 CFR 314.105(b), it is approved on the condition that you incorporate the labeling changes specified below exactly as directed and submit to FDA a copy of the final printed labeling prior to marketing:

- On the outer container Drug Facts for the 50- and 100-count caplets and the 40-count gelcaps, add a bullet before "ask a doctor" in the directions for consumers under 18 years of age (201.66(d)(4)).
- On the 50-count caplet immediate container label, add periods at the end of the Liver warning and after "Ask a doctor before use if you have liver disease." and add a space between "redness or swelling is present." and "These could be signs of a serious condition."
- On the 40-count gelcap immediate container label, under Do not use, "if you have difficulty swallowing large..." remove the extra "i" in the word "if."

LABELING

Submit final printed labeling for all SKUs with the revisions listed above but otherwise identical to the following, in the "Drug Facts" format (21 CFR 201.66) where applicable, as soon as they are available:

- 50-count capsule-shaped tablets (caplets) immediate container and outer carton (representative of the 24-, 150-, 190-, 225-, and 290-count immediate container and outer carton)
- 2-count capsule-shaped tablets (caplets) immediate/outer container (pouch)
- 100-count capsule-shaped tablets (caplets) immediate/outer container with peel-back Drug Facts label
- 40-count gelatin-coated, capsule-shaped tablets (gelcaps) immediate container and outer carton (representative of the 20- and 80-count immediate container and outer carton).

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-037**." .

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

Sincerely,

{See appended electronic signature page}

Shaw Chen, M.D.
Director (Acting)
Division of Nonprescription Clinical Evaluation
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/

SHAW T CHEN
03/26/2013