DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-872 /S-016

McNeil Consumer and Specialty Pharmaceuticals
Attention: Paula Oliver
Senior Director, Medical and Regulatory Affairs
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034-2299

Dear Ms. Oliver:

Please refer to your supplemental new drug application dated March 28, 2003, received April 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8 Hour Caplets (650 mg acetaminophen extended release tablets).

We acknowledge receipt of your submission dated July 10, 2003.

This supplemental new drug application provides for the following changes:

- change in the (b)(4)---;
- modification in (b)(4)--------process to accommodate the changes in the (b)(4)----
- revised drug product specification (changes in "description" and sample preparation procedure for "acetaminophen assay" and "content uniformity"); and
- change in the debossed logo on the tablets from "Tylenol ER" to "8 HOUR."

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

The final printed labeling (FPL) must be identical to the immediate container and carton labels submitted on July 10, 2003, and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please note, in the future, the Agency will provide guidance on wording and placement of organ-specific warnings in the labeling of drug products containing acetaminophen and that the product's labeling will need to be revised at that time to include the warning(s).

Please submit the FPL electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – NDA." Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-872/S-016". Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Curtis Rosebraugh
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