DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-872/S-018

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

Dear Ms. Oliver:

Please refer to your supplemental new drug application dated October 13, 2003, received October 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol Arthritis Pain (650 mg acetaminophen) extended release tablets.

We acknowledge receipt of your submission dated March 18, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the use of Tylenol Arthritis Pain as an alternate name to Tylenol 8 Hour for the extended release geltabs.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 18, 2004 for the 20-, 40- and 80-count packages.

The following changes should be incorporated at the time of next printing and noted in your next NDA Annual Report:

> In accordance with 21 CFR 201.61(b), revise the statement of identity to read, "acetaminophen extended release pain reliever". Additionally, enlarge the font size of the established name and pharmacological category of the product so that it shall be in a size reasonably related to the most prominent printed matter on the Principal Display Panel.

Please note, the labeling for each additional "to-be-marketed" package size that incorporates these changes must be submitted for approval. In addition, we suggest that you incorporate the aforementioned change to the statement of identity for all of the to-be-marketed package sizes.

We remind you to remove the promotional statement "New" from the Principal Display Panel after 6 months from the date of approval.

We are concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. We will provide guidance on wording and placement of organ-specific warnings in the labeling of drug products containing acetaminophen in the future.

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 the requirements for an approved NDA set forth under 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}

Curtis Rosebraugh, M.P.H., M.D.
Deputy Director
Division of Over-the-Counter Drug Products
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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