DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-872/S-021

McNeil Consumer & Specialty Pharmaceuticals
Attention: Ms. Lynn Pawelski
Executive Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Pawelski:

Please refer to your supplemental new drug application dated May 7, 2004, received May 10, 2004, 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 submissions dated August 6, 2004 and September 16, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides the following package and labeling information for Tylenol Arthritis Pain Caplets and Tylenol Arthritis Pain Geltabs:

- 40 cc, 75 cc, 120 cc, 250 cc, and 300 cc bottle packages with child resistant caps;
- 175 cc bottle package with a non-child resistant cap;
- labeling for the 24, 50, 100, 150, 190, 250, and 290 count caplets;
- labeling for the 40 and 80 count geltabs;
- and an additional packaging site.

We have 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.

Note, we are not approving labeling for (b)(4)---------- as you have proposed this package size but did not include draft labeling. You must submit labeling for this package size in a supplement for approval prior to marketing.

The final printed labeling (FPL) must be identical to the submitted draft labeling (the immediate container and carton labels listed above, submitted on August 6, 2004) and must be formatted in accordance with the requirements of 21 CFR 201.66.

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-021." Approval of this submission by FDA is not required before the labeling is used.

We recommend that the following changes should be incorporated at the time of next printing and noted in the following NDA Annual Report:

- The established name and pharmacological category (statement of identity) are presented in reverse order and are separated by the trade name. Revise the statement of identity to read, "acetaminophen extended release pain reliever" per 21 CFR 201.61(b).
- Enlarge the statement of identity to a sized reasonably related to the most prominent printed matter to comply with 21 CFR 201.61(c).
- Remove the word "New" from the promotional statements, "New Cap! Just Push & Turn" and "New! EZ-OPEN CAP", after 6 months.

We are concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. The proposed liver warning is acceptable as interim language. However, please note that we will be providing 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 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/

Charles Ganley

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