



NDA 19-872/S-014

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

Dear Ms. Oliver:

Please refer to your supplemental new drug application dated November 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8 Hour (650 mg acetaminophen) extended release tablets (geltabs) and Tylenol 8 Hour (650 mg acetaminophen) extended release caplets.

We acknowledge receipt of your amendments dated December 4 and 20, 2002, and February 4 and May 22 and 23, 2003.

This "Changes Being Effected" supplemental new drug application proposes several changes to the Drug Facts section of the label including the addition of a new "Overdose warning".

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 enclosed labeling (container and carton labels submitted December 4, 2002, with revisions as specified in your May 22, 2003, submission) 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 ten 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-014." Approval of this submission by FDA is not required before the labeling is used.

The Agency is 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 and/or NSAID's 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, M.S., Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D.
Deputy 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
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/s/

Curtis Rosebraugh
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