DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-872/S-017

McNeil Consumer and Specialty Pharmaceuticals
Attention: Cynthia Gulian
Assistant Director, CMC Regulatory
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034-2299

Dear Ms. Gulian:

Please refer to your supplemental new drug application dated September 22, 2003, received September 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8 Hour Geltabs (acetaminophen extended release tablets) 650 mg.

We acknowledge receipt of your submissions dated October 28, 2003, November 19, 2003, January 13, 2004 and March 15, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for three additional container closure systems (75cc, 230cc and 300cc) for the geltabs and the associated labeling.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter for use as in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (carton label submitted January 13, 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-017". Approval of this submission by FDA is not required before the labeling is used.

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

Statement of Identity

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.

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}

Charles Ganley, M.D.
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/

Charles Ganley
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