



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019872/S-034

APPROVAL LETTER

McNeil Consumer Healthcare
Attention: Nader Fotouhi, Ph.D.
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-22991

Dear Dr. Fotouhi:

Please refer to your supplemental new drug application dated January 8, 2010, received January 11, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8-Hour (650 mg acetaminophen) extended-release tablets.

We acknowledge receipt of your submissions dated March 11, April 14, and April 16, 2010.

This "Prior Approval" supplemental new drug application provides for a color change for the Tylenol Arthritis Pain tablet (caplet) dosage form from the currently approved all-white caplet to a new half-yellow and half-white caplet, and the associated labeling changes.

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

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labels (Tylenol Arthritis Pain "XX"-count "caplet" (representative of the 24-, 50-, 68-count (34 x 2-count pouch dispenser), 150-, 190-, 225-, and 290-count "caplet") carton labels, "XX"-count "caplet" (representative of the 24-, 50-, 100-, 150-, 190-, 225-, and 290-count "caplet") immediate container (bottle) labels, and the 2-count immediate container (pouch) label submitted March 11, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. FPL must be submitted for all the referenced count sizes. Representative labeling will not be acceptable in the FPL submission.

The final printed labeling should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)”. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 019872/S-034.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that the flag, “New Look,” should be removed 6-months after introduction into the marketplace.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Carton and Container Labels

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-19872

SUPPL-34

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

/s/

ANDREA LEONARD SEGAL

05/10/2010