



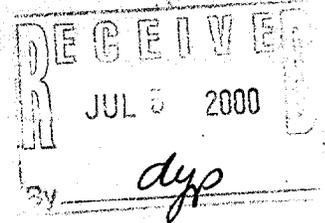
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June 27, 2000

Charles Ganley, MD, Director  
Division of OTC Drug Products (HFD 560)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
ATTN: Document Control Room  
9201 Corporate Boulevard  
Rockville, MD 20850



Dear Dr. Ganley,

Whitehall-Robins Healthcare would like to go on record with our objection to the use of the name Tylenol® Arthritis Extended Relief for the sustained release acetaminophen (APAP) product marketed by McNeil Consumer Products Co.

This product was originally marketed under the name Tylenol® Extended Relief. Each caplet contains 650 mg of acetaminophen in a sustained release formulation. Under the Tentative Final Monograph for Internal Analgesic, Antipyretic and Antirheumatic Drug Products for Over-The-Counter Human Drug Use (FR 53:1988) non-prescription analgesics are permitted to include only the indication "minor pain from arthritis" in labeling. Whitehall-Robins believes that by including "arthritis" in the trade name of their extended relief APAP product McNeil has significantly digressed from the intent of the monograph indication and the product labeling approved in their NDA.

The symptoms of arthritis include both pain and inflammation. By using the name Tylenol® Arthritis Extended Relief, McNeil is implying that the product relieves both pain and inflammation. Since acetaminophen, the sole active ingredient, is a pain reliever and not an anti-inflammatory, the product name is false and misleading to the consumer. The use of this false and misleading name in conjunction with an aggressive advertising campaign focused on arthritis have erroneously portrayed acetaminophen as an arthritis therapy without proper qualification of its true role as a pain reliever for minor aches and pains associated with arthritis. Additionally, the name provides an unfair advantage to McNeil over other OTC analgesic manufacturers who label their products in accordance with the tentative final monograph.

Whitehall-Robins has not been able to identify any record of a supplemental submission to the agency whereupon McNeil requested or received agency approval for this name

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change. Since this product was originally approved via a new drug application ( NDA 19-872), it is remarkable to us that such a significant name change would be made without prior agency approval. This serves to underline the deceptive way in which McNeil has approached this entire campaign to promote acetaminophen for the treatment of arthritis.

Whitehall-Robins believes that McNeil has demonstrated conscious disregard for the indications established by the agency for non-prescription analgesics. We believe also that these actions have created an unequal playing field for non-prescription analgesics competing for the arthritis segment of the OTC market. A trade name is significant in the arena of OTC drugs. McNeil's altering of the approved product name in such a way as to imply that the product is efficacious for arthritis is both illegal and misleading to the consumer. We respectfully request that the agency take steps to correct this situation.

Very truly yours,

*Sharon Heddish* <sup>mm</sup>

Sharon C. Heddish  
Vice President  
Regulatory Affairs Worldwide

cc:

Mr. Bradford W. Williams, Director  
Division of Labeling and Nonprescription Drug Compliance (HFD 310)

Mr. Robert Heller, OTC Compliance Team  
Division of Labeling and Nonprescription Drug Compliance (HFD 312)